feet to 8,400 feet. The average depth is approximately 8,000 feet.

[FR Doc. 81-3503 Filed 1-29-81; 8:45 am]

BILLING CODE 6450-85-M

18 CFR Part 271

[Docket No. RM79-76 (Texas-4); Order No. 126]

High-Cost Gas Produced From Tight Formations; Vicksburg UV Formation

AGENCY: Federal Energy Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Federal Energy Regulatory Commission is authorized by section 107(c)(5) of the Natural Gas Policy Act of 1978 to designate certain types of natural gas as high-cost gas where the Commission determines that the gas is produced under conditions which present extraordinary risks or costs. Under section 107(c)(5), the Commission issued a final regulation designating natural gas produced from tight formations as high-cost gas which may receive an incentive price (18 CFR § 271.703). This rule established procedures for jurisdictional agencies to submit to the Commission recommendations of areas for designation as tight formations. This final order adopts the recommendation of the Railroad Commission of Texas that the Vicksburg UV Formation be designated as a tight formation under § 271.703(d).

EFFECTIVE DATE: January 23, 1981.

FOR FURTHER INFORMATION CONTACT: Leslie Lawner, (202) 357-8307, or John Bassett, (202) 357-8589/Ting Chin, (202) 357-8595.

SUPPLEMENTARY INFORMATION:

Issued: January 23, 1981.

The Commission hereby amends § 271.703(d) of its regulations to include the Vicksburg UV Formation as a designated tight formation eligible for incentive pricing under § 271.703. The amendment was proposed in a Notice of Proposed Rulemaking by the Director, OPPR, issued October 24, 1980, (45 FR 71589, October 29, 1980),[1] based on a recommendation by the Railroad Commission of Texas (Texas) in accordance with § 271.703(c), that the Vicksburg UV Formation be designated as a tight formation.

Evidence submitted by Texas and the commenters supports Texas' assertion that the Vicksburg UV Formation meets the guidelines contained in § 271.703(c)(2). The Commission adopts the Texas recommendation.

This amendment shall become effective immediately. The Commission has found that the public interest dictates that new natural gas supplies be developed on an expedited basis, and therefore, incentive prices should be made available as soon as possible. The need to make incentive prices available immediately established good cause to waive the thirty-day publication period.

(Department of Energy Organization Act, 42 U.S.C. § 7101 *et seq.*; Natural Gas Policy Act of 1978, 15 U.S.C. § 3301-3432; Administrative Procedure Act, 5 U.S.C. 553)

For the reasons stated herein, Part 271 of Subchapter I, Title 18, *Code of Federal Regulations*, is amended as set forth below, effective January 23, 1981.

Lois D. Cashell,

Acting Secretary.

Section 271.703(d) is amended by adding new subparagraph (13) to read as follows:

§ 271.703 Tight formations.

* * * * *

(d) *Designated tight formations.* The following formations are designated as tight formations. A more detailed description of the geographical extent and geological parameters of the designated tight formations is located in the Commission's official file for Docket No. RM79-76, subindexed as indicated, and is also located in the official files of the jurisdictional agency that submitted the recommendation.

(1) *The Cotton Valley Group in Texas.* * * *

(2) *The Mancos "B" Formation in Colorado.* * * *

(3) *The Frontier Formation in Wyoming.* * * *

(4) *The Mesaverde Formation in Wyoming.* * * *

(5) *The Austin-Mississippian Formation in New Mexico.* * * *

(6) *The Mancos "B" Formation in Colorado.* * * *

(7) *The Fort Union Formation in Colorado.* * * *

(8) *The Mesaverde Formation in Colorado.* * * *

(9) *The Mancos Formation to the base of the Mancos "B" Zone in Colorado.* * * *

(10) *The Canyon Sandstone Formation in Texas.* * * *

(11) *The Wattenberg J Sand Formation in Colorado.* * * *

(12) *The Cisco Sandstone Formation in Texas.* * * *

(13) *The Vicksburg UV Formation in Texas.* RM79-76 (Texas-4)

(i) *Delineation of formation.* The Vicksburg UV Formation is found in Hidalgo County, Texas.

(ii) *Depth.* The top of the Vicksburg UV Formation is located at an approximate depth of 12,304 feet with an approximate thickness of 1,155 feet.

[FR Doc. 81-3505 Filed 1-29-81; 8:45 am]

BILLING CODE 6450-85-M

18 CFR Part 271

[Docket No. RM79-76 (Texas-5) (Order No. 127)]

High-Cost Gas Produced from Tight Formations; Vicksburg Y Formation

AGENCY: Federal Energy Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Federal Energy Regulatory Commission is authorized by section 107(c)(5) of the Natural Gas Policy Act of 1978 to designate certain types of natural gas as high-cost gas where the Commission determines that the gas is produced under conditions which present extraordinary risks or costs. Under section 107(c)(5), the Commission issued a final regulation designating natural gas produced from tight formations as high-cost gas which may receive an incentive price (18 CFR § 271.703). This rule established procedures for jurisdictional agencies to submit to the Commission recommendations of areas for designation as tight formations. This final order adopts the recommendation of the Railroad Commission of Texas that the Vicksburg Y Formation be designated as a tight formation under § 271.703(d).

EFFECTIVE DATE: January 23, 1981.

FOR FURTHER INFORMATION CONTACT: Leslie Lawner, (202) 357-8307, or John Bassett, (202) 357-8589/Ting Chin, (202) 357-8595.

SUPPLEMENTARY INFORMATION:

Issued: January 23, 1981.

The Commission hereby amends § 271.703(d) of its regulations to include the Vicksburg Y Formation as a designated tight formation eligible for incentive pricing under § 271.703. The amendment was proposed in a Notice of Proposed Rulemaking by the Director, OPPR, issued October 24, 1980, (45 FR 71589, October 29, 1980),[1] based on a recommendation by the Railroad Commission of Texas (Texas) in accordance with § 271.703(c), that the

[1] Comments were invited and two were received. No party requested a hearing in this matter, and no hearing was held.

[1] Comments were invited and two were received. No party requested a hearing in this matter, and no hearing was held.

Vicksburg Y Formation be designated as a tight formation.

Evidence submitted by Texas and the commenters supports Texas' assertion that the Vicksburg Y Formation meets the guidelines contained in § 271.703(c)(2). The Commission adopts the Texas recommendation.

This amendment shall become effective immediately. The Commission has found that the public interest dictates that new natural gas supplies be developed on an expedited basis, and therefore, incentive prices should be made available as soon as possible. The need to make incentive prices available immediately established good cause to waive the thirty-day publication period.

(Department of Energy Organization Act, 42 U.S.C. § 7101 *et seq.*; Natural Gas Policy Act of 1978, 15 U.S.C. § 331–3432; Administrative Procedure Act, 5 U.S.C. 553)

For the reasons stated herein, Part 271 of Subchapter I, Title 18, *Code of Federal Regulations*, is amended as set forth below, effective January 23, 1981.

By the Commission.

Lois D. Cashell,

Acting Secretary.

Section 271.703 is amended by adding new subparagraph (d)(14) to read as follows:

§ 271.703 Tight formations.

* * * * *

(d) *Designated tight formations.* The following formations are designated as tight formations. A more detailed description of the geographical extent and geological parameters of the designated tight formations is located in the Commission's official file for Docket No. RM79–76, subindexed as indicated, and is also located in the official files of the jurisdictional agency that submitted the recommendation.

(1) *The Cotton Valley Group in Texas.* * * *

(2) *The Mancos "B" Formation in Colorado.* * * *

(3) *The Frontier Formation in Wyoming.* * * *

(4) *The Mesaverde Formation in Wyoming.* * * *

(5) *The Austin-Mississippian Formation in New Mexico.* * * *

(6) *The Mancos "B" Formation in Colorado.* * * *

(7) *The Fort Union Formation in Colorado.* * * *

(8) *The Mesaverde Formation in Colorado.* * * *

(9) *The Mancos Formation to the base of the Mancos "B" Zone in Colorado.* * * *

(10) *The Canyon Sandstone Formation in Texas.* * * *

(11) *The Wattenberg J Sand Formation in Colorado.* * * *

(12) *The Cisco Sandstone Formation in Texas.* * * *

(13) *The Vicksburg UV Formation in Texas.* * * *

(14) *The Vicksburg Y Formation in Texas.* RM79–76 (Texas-5)

(i) *Delineation for formation.* The Vicksburg Y Formation is found in Hidalgo County, Texas.

(ii) *Depth.* The top of the Vicksburg Y Formation in the McAllen Ranch Field is located at an approximate depth of 13,595 feet in the north and 13,244 feet in the south and ranges in thickness from approximately 1,955 feet in the north to 1,717 feet in the south.

[FR Doc. 81-3500 Filed 1-29-81; 8:45 am]

BILLING CODE 6450-85-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 131

[Docket No. 77N-0143]

Cultured and Acidified Milks, Cultured and Acidified Buttermilks, Yogurts, and Eggnog; Standards of Identity

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document establishes standards of identity for cultured milk, cultured lowfat milk, acidified milk, acidified lowfat milk, yogurt, lowfat yogurt, nonfat yogurt, and eggnog. Second, it renames the proposed standards for cultured buttermilk and acidified buttermilk as cultured skim milk and acidified skim milk, respectively. Finally, it incorporates provisions for buttermilk, lowfat buttermilk, and skim milk buttermilk into the appropriate cultured and acidified product standards. The yogurt standards established by this rule are based on consideration of the international standards for these foods developed by the Codex Alimentarius Commission. The purpose of this action is to promote honesty and fair dealing in the interest of consumers and to facilitate international trade.

DATES: Effective July 1, 1983 for all affected products initially introduced or initially delivered for introduction into interstate commerce on or after this date; voluntary compliance beginning March 31, 1981; objections by March 2, 1981.

ADDRESS: Written objections to the Dockets Management Branch (formerly the Hearing Clerk's office) (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Eugene T. McGarrahan, Bureau of Foods (HFF–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–245–1155.

SUPPLEMENTARY INFORMATION: The Food and Drug Administration (FDA) issued a proposal in the Federal Register of June 10, 1977 (42 FR 29919) to establish standards of identity for cultured buttermilk, acidified buttermilk, yogurt, lowfat yogurt, nonfat yogurt, cultured milk, cultured lowfat milk, acidified milk, acidified lowfat milk, and eggnog. The purpose of the proposed action was to standardize the composition and names of these nonstandardized foods which would, in turn, make informed consumer choices and interstate sale of the products easier. Interested persons had until October 10, 1977 to comment.

In the preamble to the proposal, FDA stated that informal consideration was being given to the international Codex Alimentarius Commission recommended standards for plain and plain sweetened yogurt (Codex standard No. A–11(a)) and flavored yogurt (Codex standard No. A–11(b)). At that time only standard A–11(a) had been made final and sent to governments of member countries for acceptance. The United States, as a member nation of the Joint Food and Agriculture Organization/World Health Organization (FAO/WHO), is under treaty obligation to consider all recommended international standards. The rules of procedure of the Codex Alimentarius Commission state that a standard may be accepted by a participating country in one of three ways: full acceptance, target acceptance, or acceptance with specified deviations.

Formal consideration of these standards for acceptance was deferred until standard A–11(b) was made final. Since publication of the proposal, standard A–11(b) has been made final and sent to governments of member countries for acceptance. Since no substantive changes were made to the Codex standard A–11(b) between the draft and final versions, the agency believes that formal consideration, in essence, has been given to the acceptance of both of the Codex recommended standards. Each of the two Codex standards, A–11(a) and (b), is included in this document for informational purposes. The final regulations establishing standards of identity for yogurt, lowfat yogurt, and nonfat yogurt include both changes from

the proposed standards based on the comments received and provisions of the two Codex standards (A–11(a) and (b)) which are being adopted with specified deviations.

Standard for Yoghurt (Yogurt) and Sweetened Yoghurt (Sweetened Yogurt)—(A–11–(a))

1. Definitions

1.1 Yoghurt is a coagulated milk product obtained by lactic acid fermentation through the action of Lactobacillus bulgaricus and Streptococcus thermophilus, from milk and milk products as listed in 2.3 and with or without those listed in 2.5. The microorganisms in the final product must be viable and abundant.

1.2 Sweetened yoghurt is yoghurt to which one or more sugars only have been added.

1.3 'Sugars' mean any carbohydrate sweetening matter.

2. Essential Composition and Quality Factors

2.1 *Yoghurts*

2.1.1 *Yoghurt*

Minimum milkfat content: 3.0% m/m

Minimum milk solids non-fat content: 8.2% m/m

2.1.2 *Partially skimmed yoghurt*

Maximum milkfat content: less than 3.0% m/m

Minimum milkfat content: more than 0.5% m/m

Minimum milk solids non-fat content: 8.2% m/m

2.1.3 *Skimmed yoghurt*

Maximum milkfat content: 0.5% m/m

Minimum milk solids non-fat content: 8.2% m/m

2.2 *Sweetened yoghurts*

Yoghurt, partly skimmed yoghurt and skimmed yoghurt complying with the requirements of sections 2.1.1 and 2.1.2 and 2.1.3 respectively, and containing sugars. The compositional requirements refer to the milk part of the sweetened yoghurts.

2.3 *Essential raw materials*

—Pasteurized milk or concentrated milk, or

—Pasteurized partly skimmed milk or concentrated partly skimmed milk, or

—Pasteurized skimmed milk or concentrated skimmed milk, or

—Pasteurized cream, or

—A mixture of two or more of these products.

2.4 *Essential additions*

—Cultures of Lactobacillus bulgaricus and Streptococcus thermophilus.

2.5 *Optional additions*

—Milk powder, skimmed milk powder, unfermented buttermilk, concentrated whey, whey powder, whey proteins, whey protein concentrate, water-soluble milk proteins, edible casein, caseinates, manufactured from pasteurized products.

—Cultures of suitable lactic acid producing bacteria in addition to those in 2.4.

—Sugars (in sweetened yoghurt only).

3. Food Additives

None.

4. Labelling

In addition to Sections 1, 2, 4 and 6 of the General Standard for the Labelling of Prepackaged Foods (Ref. No. CAC/RS 1–1969) the following specific provisions apply:

4.1 *The name of the food*

The name of the product shall be Yoghurt, or Yogurt, subject to the follow provisions:

4.1.1 Yoghurt with not less than 3.0% milkfat content should be designated as yoghurt unqualified.

4.1.2 For yoghurt with less than 3.0% milkfat but with more than 0.5% milkfat the designation shall include partly skimmed, low fat or any other suitable qualifying description. Accompanying the name of the food shall be a milkfat statement in multiples of 0.5%, e.g. 1.0%, 1.5%, 2.0% etc. whichever is closest to the actual milkfat content of the yoghurt.

4.1.3 For yoghurt with less than 0.5% m/m milkfat content the designation shall include skimmed or any other suitable qualifying description.

4.1.4 The provisions given in 4.1.1, 4.1.2 and 4.1.3 apply also to yoghurt to which sugar or sugars have been added in accordance with section 2.2, with the proviso that the designations concerned shall be accompanied by the term "Sweetened".

4.1.5 Where milk other than cow's milk is used for the manufacture of the product or any part thereof, a word or words denoting the animal or animals from which the milk has been derived should be inserted immediately before or after the designation of the product except that no such insertion need be made if the consumer would not be misled by its omission.

4.2 *List of ingredients*

A complete list of ingredients shall be declared on the label in descending order of proportion.

4.3 *Net contents*

The net contents shall be declared by weight in either the metric ("Système International" units) or avoirdupois or both systems of measurement or by volume in one or more of the following systems of measurement: metric ("Système International"), U.S. or British units as required by the country in which the product is sold.

4.4 *Name and address*

The name and address of the manufacturer, packer, distributor, importer or vendor, shall be declared.

4.5 *Country of origin (manufacture)*

The country of manufacture of the food shall be declared except that foods sold within the country of manufacture need not declare the country of manufacture.

4.6 *Date marking*

There shall be an indication in clear of the date of production, that is, the date the final product was packaged for final sale or the sell-by date.

Standard for Flavoured Yoghurt and Products Heat-Treated After Fermentation—(A–11–(b))

1. Scope

This standard applies to flavoured yoghurt and the products heat-treated after fermentation.

2. Definitions

2.1 *Flavoured Yoghurt* is a coagulated milk product obtained by lactic acid fermentation through the action of Lactobacillus bulg. and Strep. thermophilus from milk products as listed in 3.3.1, to which have been added, flavouring foods or other flavouring ingredients as listed in 3.3.2 with or without optional ingredients. The micro-organisms in the final product must be viable and abundant.

2.2 *Products heat-treated after fermentation* are products as described under 2.1 which have been submitted to a heat-treatment after fermentation. They need not contain viable and abundant micro-organisms.

2.3 *"Sugars"* mean any carbohydrate sweetening matter.

3. Essential Composition and Quality Factors

3.1 The milk part of flavoured yoghurts shall comply with the requirements for yoghurts as specified under 3.2.

3.2 *Yoghurts*

3.2.1 *Yoghurt*

Minimum milkfat content: 3.0% m/m

Minimum milk solids non-fat content: 8.2% m/m

3.2.2 *Partially skimmed yoghurt*

Maximum milkfat content: less than 3.0% m/m

Minimum milkfat content: more than 0.5% m/m

Minimum milk solids non-fat content: 8.2% m/m

3.2.3 *Skimmed yoghurt*

Maximum milkfat content: 0.5% m/m

Minimum milk solids non-fat content: 8.2% m/m

3.3 *Essential raw materials*

3.3.1 Pasteurized milk or concentrated milk, or

—Pasteurized partly skimmed milk or concentrated partly skimmed milk, or

—Pasteurized skimmed milk or concentrated skimmed milk, or

—Pasteurized cream, or

—A mixture of two or more of these products.

3.3.2 Natural flavouring ingredients such as fruit (fresh, canned, quick frozen, powdered), fruit purée, fruit pulp, jam, fruit syrup, fruit juice, honey, chocolate, cocoa, nuts, coffee, spices and other harmless natural flavouring foods.

3.4 *Essential additions*

—Cultures of Lactobacillus bulgaricus and Streptococcus thermophilus.

3.5 *Optional additions*

—Sugars

—Milk powder, skimmed milk powder, unfermented buttermilk, concentrated whey, whey powder, whey proteins, whey protein concentrate, water-soluble milk proteins, edible casein, caseinates, manufactured from pasteurized products.

—Cultures of suitable lactic acid producing bacteria in addition to those in 3.4.

—Harmless natural colouring ingredients.

4. Food Additives

4.1 *Flavours*

The terms below are defined in the "List of Additives Evaluated for their Safety-in-use in Food", CAC/FAL 1–1973 and Supp. 1.

4.1.1 Natural flavours and flavouring substances.

4.1.2 Natural identical flavouring substances.

4.1.3 Artificial flavouring substances appearing in the Codex List, CAC/FAL 1–1973 and Supp. 1.

4.2 *Food Colours (which come exclusively from flavouring substances as a result of carry-over)*

	Colour index (1971) No.	Maximum level (mg/kg)
Tartrazine	19140	18
Sunset Yellow FCF or Orange Yellow S	15985	12
Cochineal or Carminic Acid*	75470	20
Carmoisine or Azorubine	14720	57
Ponceau 4R or Cochineal Red A	16255	48
Erythrosine BS	45430	27
Indigo Carmine or Indigotine	73015	6
Green S or Acid Brilliant Green BS or Lissamine Green*	44090	2
Caramel Colours		150
Black PN or Brilliant Black BN	28440	12
Beetreet Red or Betanin		250
Chocolate Brown FB*		30
Red 2 G	18050	30
F.D. and C. Blue No. 1 (Brilliant Blue FCF)	42090	
Other Colouring ingredients extracted from natural fruit and vegetable sources*		

*Not yet cleared toxicologically.

4.3 *Stabilizers*

Furcellaran, Xanthan gum, Arabic, Locust (Carob) bean gum*, Karaya gum, Guar gum*, Tragacanth gum*, Agar-agar, Carrageenan, Sodium carboxymethylcellulose (cellulose gum), Sodium, potassium, calcium and ammonium alginates (Algin), Propylene glycol alginate	5000 mg/kg
Pectins	10 g/kg
Gelatine	10 g/kg
Starches and modified starches appearing in the Codex List (CAL/FAL 1–1973) and supplement [1]	10 g/kg

*Not yet cleared toxicologically.
[1] Endorsed by the Codex Committee on Food Additives.

4.4 *Preservatives (which come exclusively from flavouring substances as a result of carry-over)*

Sorbic acid and its sodium, potassium and calcium salts, sulphur dioxide, benzoic acid at levels in the final product resulting from those permitted in individual Codex standards for fruits and fruit based products, or within a maximum of 50 mg/kg (singly or in combination) in the final product.

5. Labeling

In addition to Sections 1, 2, 4 and 6 of the Recommended International General Standard for the Labelling of Prepackaged Foods (Ref. No. CAC/RS 1–1969), the following specific provisions apply:

5.1 *The name of the food*

5.1.1 The name of the product shall be Flavoured Yoghurt, subject to the following provisions:

5.1.1.1 Yoghurt with not less than 3.0% milkfat content should be designated as yoghurt unqualified.

5.1.1.2 For yoghurt with less than 3.0% milkfat but with more than 0.5% milkfat the designation shall include partly skimmed, low fat or any other suitable qualifying description. Accompanying the name of the food shall be a milk fat statement in multiples of 0.5%, e.g. 1.0%, 1.5%, 2.0% etc. whichever is closest to the actual milk fat content of the yoghurt.

5.1.1.3 For yoghurt with less than 0.5% m/m milkfat content the designation shall include skimmed or any other suitable qualifying description.

5.1.2 The name of the product heat-treated after fermentation shall be that specified in national regulations, subject to provisions 5.1.1.1, 5.1.1.2 and 5.1.1.3.*

5.1.3 Where milk other than cow's milk is used for the manufacture of the product or any part thereof, a word or words denoting the animal or animals from which the milk has been derived should be inserted immediately before or after the designation of the product except that no such insertion need be made if the consumer would not be misled by its omission.

5.2 *List of Ingredients*

A complete list of ingredients shall be declared on the label in descending order of proportion in accordance with sub-sections 3.2(b) and (c) of the Recommended International General Standard for the Labelling of Prepackaged Foods.

5.3 *Net Contents*

The net contents shall be declared by weight in either the metric ("Système International" units) or avoirdupois or both systems of measurement or by volume in one or more of the following systems of measurement: metric ("Système International"), U.S. or British units as required by the country in which the product is sold.

5.4 *Name and Address*

The name and address of the manufacturer, packet, distributor, importer or vendor shall be declared.

5.5 *Country of origin (manufacture)*

The country of manufacture of the food shall be declared except that foods sold within the country of manufacture need not declare the country of manufacture.

5.6 *Date marking*

There shall be an indication in clear of the date of production, that is, the date the final product was packaged for final sale or the sell-by date of minimum durability date.

5.7 *Lot identification**

Each container shall be permanently marked in code or in clear to identify the producing factory and the lot.

One hundred and sixteen letters, each containing one or more comments, were received in response to the June 10, 1977 proposal. The issues raised in the comments and the FDA's responses are as follows:

1. *Label declaration of terms "pasteurized" and "ultra-pasteurized".*

*The governments are requested to notify the specific names exclusively provided in their national regulations for the products heat-treated after fermentation.

*Provision proposed to be included in the Standard by the Secretariat in line with the decision taken by the Committee for other standards discussed at the 18th Session (see paras 84, 93 and 107) and in accordance with the recommendation of the Codex Committee on Food Labelling.

Several comments expressed the opinion that use of either term "pasteurized" or ultra-pasteurized" accompanying the name of any of the cultured or acidified foods, as proposed, is potentially misleading to consumers because it could be construed to imply that all of the ingredients in the foods underwent the designated heat process when , in fact, only the dairy ingredients are pasteurized or ultra-pasteurized.

The agency agrees with these comments and has deleted the terms "pasteurized" or "ultra-pasteurized" in conjunction with the names of cultured or acidified products from §§ 131.111, 131.112, 131.136, 131.138, 131.144, 131.146, 131.200, 131.203, 131.206, as set forth below. The agency concludes that the use of these terms is unnecessary because the dairy ingredients that may be used in the manufacture of these foods are required by applicable standards of indentity to be either pasteurized or ultra-pasteurized. The agency advises that it is the responsibility of the manufacturers to take the precautionary measures necessary to assure that ingredients to be added to these foods after culturing, such as bulky flavor to yogurts, or milkfat or butterfat flakes or granules to buttermilks, do not contaminate the food.

2. *Consistency with the Pasteurized Milk Ordinance.* One comment expressed concern that the proposed standards of identity for these dairy products be consistent with the definitions for the foods found in the "Grade A Pasteurized Milk Ordinance—1965 Recommendations of the U.S. Public Health Service" (PMO) because the PMO definitions have been adopted as law or regulation by many States.

The agency points out that the PMO definitions and the proposed regulations are consistent and, in fact, the proposed standards of identity were based on the 1965 PMO definitions. Further, it should be noted that FDA and the National Conference on Interstate Milk Shipments formally recommended that the State milk regulatory agencies adopt the proposed standards of identity, herein being made final, in place of the previously recommended PMO definitions for these products. The basis for this recommendation was that it would promote further uniformity in the composition of dairy products and in the labeling of these foods which become a part of interstate commerce.

3. *Alternative Forms and Types of Dairy Ingredients.* Several comments requested that alternative forms and types of dairy ingredients be permitted for use as the basic ingredients in yogurts and other cultured and acidified dairy products. The various reasons given were: (1) all of these ingredients are derived from milk; (2) when nonfat dry milk is reconstituted and used in a food, 21 CFR 101.4 allows it to be declared as "skim milk" in the ingredient statement; (3) ingredient statement declaration of nonfat dry milk and water necessary for reconstitution would adequately inform consumers of the type of dairy ingredients used; (4) use of any form and type of dairy ingredient that maintains the product's physical characteristics and nutritive content is consistent with the agency's philosophy of flexibility of ingredient use; and (5) yogurt produced from reconstituted nonfat dry milk is organoleptically indistinguishable from yogurt produced from fresh fluid skim milk.

The agency rejects the arguments presented in these comments. Traditionally, the dairy products included in the proposal have been made from fresh, fluid dairy ingredients. Concentrated or dried dairy ingredients are being permitted only to adjust the milk solids content. No sound reasons supporting the inclusion of alternative forms and types of dairy ingredients as basic ingredients for the manufacture of yogurts and other cultured and acidified dairy products were presented to refute the agency's conclusions regarding consumer expectations. Therefore, the agency concludes that the requested alternative forms and types of dairy ingredients will not be allowed as basic ingredients for the manufacture of yogurts and other cultured and acidified dairy products. The agency advises that any yogurt or other cultured or acidified dairy product that is being made with alternative forms and types of dairy ingredients not allowed by the standards of identify set forth below is a nonstandardized food and is required to be labeled in accordance with 21 CFR 101. For example, the name for a yogurt made solely from reconstituted milk would be "yogurt made from reconstituted milk" or another similar name.

4. *Milk-derived ingredients.* One comment proposed disallowing the use of all milk-derived ingredients and allowing the use of only concentrated skim milk and nonfat dry milk under the "other optional ingredients" provision because it feared that the proposed standards, if adopted, would allow "for processing a group of synthetic products that can be sold as and under the name of natural dairy products." The comment pointed out that "any number of combinations of milk, whey, and caseinate could be used to meet the milk solids not fat and protein requirements of the proposed standards," thereby making some of the products so produced deceptive to consumers.

The agency disagrees with this comment because milk-derived ingredients may be used only to increase the milk solids not fat content above the minimum set in each standard, not to meet the minimum. Furthermore, use of these ingredients may not result in a lowering of the ratio of protein to total nonfat solids content or of the Protein Efficiency Ration (PER). The standards clearly impose a limit on the use of these ingredients and there is no need to disallow their use.

Two comments proposed a definition for the term "milk-derived ingredients" which excluded some commonly used milk-derived ingredients. They maintained that the use of these excluded milk-derived ingredients would require products to be labeled "nondairy" and would interfere with the use of the "Grade A" designation on the label, as provided in the PMO.

The agency advises that the term "nondairy" is used by manufacturers, either voluntarily or as required by State laws, to distinguish their products which simulate dairy products from the dairy products being simulated. FDA does not require the use of the term "nondairy". In fact, if a milk-derived ingredient such as sodium caseinate is used in product, FDA advises manufacturers that the source of the ingredient should be noted in the ingredient declaration, that is * * * sodium caseinate (a milk derivative) * * *.

FDA would also like to correct the apparent misconception that milk-derived ingredients are not allowed for use in "Grade A" dairy products under the provisions of the 1965 PMO. Such ingredients are allowed under the 1965 PMO Definition Q "Optional Ingredients".

The agency is specifying the milk-derived ingredients permitted by revising paragraph (e)(1) of §§ 131.111, 131.136, 131.144, and 131.170; (d)(1) of §§ 131.112, 131.138, 131.146; and (c)(1) of §§ 131.200, 131.203 and 131.206 to replace the term "milk-derived ingredients" with a list of suitable ingredients that have been traditionally used in these products. Therefore, the final regulation is being revised to include the following ingredients: buttermilk, whey, lactose, lactalbumins, lactoglobulins, or whey modified by partial or complete removal of lactose and/or minerals.

The two comments above also suggested that the ingredients included in their proposed definition be permitted for use in unlimited quantities as long as

the ratio of protein to total nonfat solids content and the PER of all protein present are not decreased.

The agency does not agree with this suggestion. Because the comment does not explain its intended meaning of the phrase "unlimited quantities", the agency can only interpret this under its plain meaning. As already discussed, these milk-derived ingredients may be used only after the required milk solids not fat minima have been met.

5. *Determining level of acidity.* One comment suggested that a method for potentiometric determination of acidity (pH value) be provided for in addition to the Association of Official Analytical Chemists (AOAC) titration method provided for in the proposal. The comment maintained that flavors and colors many times interfere with a precise determination of the colorimetric endpoint of the titration.

FDA agrees and paragraph (f)(3) of §§ 131.111, 131.136, and 131.144; (e)(3) of §§ 131.112, 131.138, and 131.146; and (d)(3) of §§ 131.200, 131.203, and 131.206 have been revised to allow an equivalent potentiometric method to be used to determine acidity, as well as the AOAC titration method.

6. *Protein Efficiency Ratio.* One comment raised the possibility that the results of the Protein Efficiency Ratio (PER) method may not be adequate for FDA to enforce standards and, as a result, may allow "products of inferior nutritional quality as compared to a natural milk product" to enter the market.

The agency believes that PER test results can be used to enforce standards in those instances where ingredients have been added that have the effect of lowering the PER. It is recognized that the nutrient composition in relation to the bulk of some foods prevents incorporation of those foods, in their original form, in the biological evaluation test diet at the recommended nutrient levels (Official Methods of Analysis of the AOAC). Processes such as freeze-drying and/or lipid extraction may be necessary to reduce the volume of the product or to remove interfering substances before testing of the products.

A second comment suggested that protein quality and quantity limitations should be specified by insertion of the following phrase in paragraph (a) of each standard: "not less than 2.7 percent protein having a Protein Efficiency Ratio (PER) not less than that of whole milk (108 percent of casein)". This limitation would allow any safe and suitable dairy-derived ingredients, fluid or dry, to be used.

The agency does not concur with this suggestion. No data supporting this suggestion were submitted. FDA advises that while this 2.7 percent protein minimum requirement was once proposed for the ice cream standard, it has no bearing on the products included in this final regulation. Notwithstanding this fact, the proposed 2.7 percent protein minimum requirement for ice cream was subsequently revoked because of the possibility of a reduction in nutrient levels in some frozen desserts. This notice of revocation was published in the **Federal Register** of February 3, 1978 (43 FR 4596).

7. *Vitamin addition.* In response to FDA's request for information, two comments suggested that the agency provide for the addition of vitamins A and D to cultured milk and cultured lowfat milk. One of these comments further suggested allowing the addition of vitamins A and D to the foods covered in all the proposed standards.

FDA partially agrees with these comments and is providing for optional vitamin addition in a new paragraph (b) added to §§ 131.111, 131.112, 131.136, and 131.138. Appropriate labeling provisions are being added to paragraph (g) of §§ 131.111 and 131.136 and paragraph (f) of §§ 131.112 and 131.138. Vitamins A and D will not be permitted in yogurts and eggnog at this time because these two foods traditionally do not contain added vitamins. However, the agency invites any interested person who believes that adding vitamins to these products should be allowed to submit a petition presenting reasonable grounds in support of such action.

8. *Cultured and acidified products.* Several comments made suggestions relative to the proposed standards for buttermilk. Five comments requested that the proposed cultured buttermilk standard be revised to provide for a milkfat content of up to 2.0 percent rather than the proposed 0.5 percent and to require that a declaration of the percent milkfat appear on the label with the name of the food. They contended that presently marketed cultured buttermilk, as defined in the PMO since 1965, is not only a nonfat milk product but also includes products having the higher milkfat content. Further, these comments sought to either establish a separate standard for "cultured wholemilk buttermilk" with a minimum milkfat level of 3.25 percent, as in the PMO definition for wholemilk buttermilk, or to revise the proposed cultured buttermilk standard to include the names "cultured nonfat buttermilk" and "cultured wholemilk buttermilk". This comment pointed out that if the separate standard for "cultured wholemilk buttermilk" is established, then "cultured nonfat buttermilk" should be included in the "cultured buttermilk" standard since the milkfat content of the nonfat product falls in the 0–2.0 percent range suggested for cultured buttermilk. Similar changes were suggested for the acidified milk standards of identity.

One of the comments suggested alternative names for the proposed standards for cultured and acidified products. It suggested changing the names of the standards for acidified milk and cultured milk, acidified buttermilk and cultured buttermilk, and acidified lowfat and cultured lowfat milk to "acidified wholemilk buttermilk" and "cultured wholemilk buttermilk", "acidified nonfat (or skim) buttermilk" and "cultured nonfat (or skim) buttermilk", and "acidified buttermilk" and "cultured buttermilk", respectively. One comment suggested that "acidified skim milk" would be a more appropriate name than "acidified buttermilk" for the products described in the proposed § 131.113. Each of these standards would provide for the use of appropriate optional ingredients. It was also suggested that the products "acidified buttermilk" and "cultured buttermilk" should have their names accompanied by label declarations of the percent milkfat content.

The agency agrees with the intent of these comments. To accomplish the purposes set forth by their suggestions, FDA is revising and redesignating § 131.113, acidified buttermilk, as § 131.144, "acidified skim milk" and § 131.114, cultured buttermilk, as § 131.146, "cultured skim milk". To maintain the alphabetical order of Part 131 and accommodate the addition of §§ 131.144 and 131.146, the standard of identity for skim milk (§ 131.145) is being redesignated as § 131.143. In addition, in order to include cultured and acidified buttermilk and lowfat buttermilk in the standards for cultured and acidified milk and lowfat milk, FDA is revising §§ 131.111(e), 131.112(d), 131.136(e), and 131.138(d) by adding the optional ingredients that may be used in buttermilk (items (6), (7), (8), and (9) of each paragraph), and to include provisions for naming buttermilk products such as "acidified buttermilk", "cultured buttermilk", "acidified lowfat buttermilk" and "cultured lowfat buttermilk". Also, FDA is revising §§ 131.144(g) and 131.146(f) to include provisions for naming cultured and acidified skim milk products other than buttermilk as well as for buttermilk.

The following table summarizes the name and section number changes for the standards set forth below.

Proposal		Final Regulation	
§ 131.111	Acidified milk	§ 131.111	No change.
§ 131.112	Cultured milk	§ 131.112	No change.
§ 131.113	Acidified buttermilk.	§ 131.144	Acidified skim milk.
§ 131.114	Cultured buttermilk.	§ 131.146	Cultured skim milk.
§ 131.136	Acidified lowfat milk.	§ 131.136	No change.
§ 131.138	Cultured lowfat milk.	§ 131.138	No change.
§ 131.170	Eggnog	§ 131.170	No change.
§ 131.200	Yogurt	§ 131.200	No change.
§ 131.203	Lowfat yogurt	§ 131.203	No change.
§ 131.206	Nonfat yogurt	§ 131.206	No change.

One comment expressed the opinion that the use of traditional cultured product names in the names of acidified milk and acidified lowfat milk, for example, "kefir milk" as part of the name "acidified kefir milk" is false and misleading to consumers. In addition, the comment requested that the word "imitation" precede the name of the food when names of characterizing microorganisms are included in the name of the food. Consumers would then be alerted that certain characteristics of the food are not due to the action of characterizing microorganisms.

FDA disagrees with these comments. FDA points out that the acidified milk standards were designed to provide for acidified versions of any cultured milks that would be included in the general cultured milk standards. The proposed standards clearly permitted the use of names of microorganisms in the name of the food only when the microorganisms are present and impart the appropriate characteristics to the food. Therefore, in addition to coagulating dairy ingredients and imparting tartness to the product, either of which may be accomplished with food grade acidulants, the characterizing organisms must be present in the product to impart traditionally expected organoleptic characteristics to the food. FDA concludes that, rather than misleading consumers, the presence of the traditional name with the word "acidified" fully informs the consumer that there are basic differences in the product. Because the term "imitation" is required by regulation to be applied to foods that are nutritionally inferior to the products being imitated, the agency does not find it appropriate to use this term in the case of products where characterizing microorganisms are included in the names of standardized acidified products.

Two comments pointed out that it is common practice to color butter flakes and granules for the sake of standardization and uniformity. They interpret the prohibition on use of color that simulates the color of milkfat or butterfat as being extended to the butter flakes and granules. They requested that the proposed limitation on the use of color be removed.

FDA points out that since the butter flakes or granules are prepared from butter which may, under the Butter Act of 1923, contain color, it is reasonable to expect that the butter flakes or granules will also contain color. However, FDA concludes that it would not be in the best interests of the consumer to allow the addition of this color because it could make the products appear to be better or of greater value than they are.

FDA is aware that some companies manufacture products called "buttermilk flakes" or "flakes for buttermilk" which contain no butterfat. These "butter flakes substitutes" do contain milkfat, as well as color and other dairy ingredients provided for in the standards of identity for "cultured buttermilk" and "acidified buttermilk". The purpose of the flakes or granules is to give the cultured and acidified buttermilks physical characteristics similar to those of buttermilk obtained from the churning of cream into butter. The same effect is obtained using flakes or granules made from either butterfat or milkfat. FDA concludes that both forms of flakes and granules should be provided for in §§ 131.111(e), 131.112(d), 131.136(e), 131.138(d), 131.144(e), and 131.146(d), as set forth below. However, flakes or granules made with milkfat should not be declared as "butter flakes" or "butter granules" in either the name or the ingredient statement of cultured and acidified buttermilks. Instead, they must be declared as required by 21 CFR 101.3(e).

One comment requested that salt be permitted for optional use in acidified buttermilks and cultured buttermilks as a flavor potentiator.

FDA points out that the optional use of salt was permitted by the proposed standards of identity for acidified buttermilk and cultured buttermilk. In conjunction with providing for buttermilk within each of the cultured and acidified milk standards, as discussed above, salt has been included as an optional ingredient in §§ 131.111(e), 131.112(d), 131.136(e), 131.138(d), 131.144(e), and 131.146(d), as set forth below.

9. *Eggnog.* Several comments objected to allowing only those colors that do not impart a color simulating that of egg yolk, milkfat, or butterfat to be added to eggnog. They stated that inconsistencies in egg yolk color, due to season of the year, type of feed, or other factors, make the use of color necessary to achieve the consistent, uniform color that consumers expect of eggnog. Further, they stated that ingredient labeling will adequately inform consumers about the use of color.

FDA does not agree with these comments. The agency recognizes that egg yolk color is affected by several variables. However, the quantity of egg yolk ingredient required by the proposed standard would not color eggnog as deeply as most eggnogs in today's market are colored. The use of yellow color is deceptive to consumers in that it suggests that the egg yolk content of the food is higher than it actually is. Ingredient labeling does not rectify this situation since the mere declaration of color does not tell the consumer that there is not as much egg in the product as there appears to be. Therefore, FDA concludes that the proposed limitation on the type of color that may be added to eggnog will be retained because it is reasonable and will prevent consumer deception.

Two manufacturers expressed concern that their dry eggnog mixes, which are sold primarily to hospitals and other health care facilities, will not comply with the proposed standard of identity for eggnog. They believe that they would be required to label their products as "imitation." This belief is based on the fact that their products, when reconstituted, are either low in milkfat or egg yolk and, from a nutritional standpoint, low in cholesterol and/or sodium, or high in calories or protein. The manufacturers believe that the term "imitation" or any other qualifying term accompanying the name of their products will have a detrimental effect on patients' acceptability of the product.

The manufacturers further suggested modifying the proposed standard by changing the name of the food to "dairy eggnog," "holiday eggnog," or "party eggnog," applying the proposed eggnog standard to fluid products only, and permitting "lowfat" and "low cholesterol" label declarations, or alternatively, the use of a legend such as "a special institutional product" on the label. All of these changes would permit use of the name "eggnog" on dry mixes.

FDA rejects the arguments presented by these comments. The agency recognizes that egg and milk type beverages have long been a favorite vehicle for introduction of additional nutrients into the diets of patients. However, "eggnog" is being misused on the products cited in the comments. Eggnog enjoys a long time reputation among consumers as a fresh, fluid dairy product containing, basically, eggs, milk

and/or cream, and sugar. Furthermore, 46 States have standards of identity establishing minimum levels of egg yolk and/or milkfat for eggnog. Therefore, eggnog and its composition have become well established. When the products described in the comments are reconstituted, they do not compositionally resemble eggnog in that they are lower in egg yolk and/or milkfat than the traditional product and their nutrient content has been modified. The fact that at least two of the products cited contain less than the traditionally expected quantity of a valuable constituent (egg yolk solids and/or milkfat) places those products in violation of the Federal Food, Drug, and Cosmetic Act. The name "eggnog" cannot be used on the labels of these products without further qualifying terms such as "imitation" or "substitute" in accordance with 21 CFR 101.3. FDA, therefore, concludes that no changes in the nomenclature provisions of the proposed standard are warranted.

Citing the fact that the PMO definition includes no minimum milk solids not fat requirement, several comments expressed the opinion that the proposed minimum was too high and should be eliminated. One comment suggested that it should at least be reduced to 6.25 percent. No data were submitted in support of the 6.25 percent figure. All the comments maintained that eggnog is characterized by the egg yolk solids and milkfat content rather than the milk solids not fat content.

FDA agrees that the 9.0 percent minimum milk solids not fat may be too high inasmuch as the minimum level for milk and skim milk is 8.25 percent. However, the agency believes that eliminating the minimum milk solids not fat level or reducing the minimum to 6.25 percent would not assure that a reasonable milk solids not fat level is maintained. This consideration is consistent with other standards of identity for milk and milk products. Further, when an 8.25 percent milk solids not fat milk is combined with cream to adjust the milkfat level to 6.0 percent, the milk solids not fat level will be at least 8.25 percent since the cream used to adjust the milkfat level also contains milk solids not fat. FDA, therefore, concludes that a minimum milk solids not fat level of 8.25 percent is reasonable and is so providing in § 131.170(a), as set forth below.

Several comments requested that the addition of volatile flavors and colors to eggnog be allowed after pasteurization or ultra-pasteurization.

FDA advises that the manufacturers are not restricted to the use of volatile flavors and colors because there are flavorings and colors on the market that are sufficiently heat resistant to withstand pasteurization and ultra-pasteurization temperatures.

FDA, therefore, denies this request because the greatest degree of public health protection is achieved when all of the ingredients, including flavors and colors, are pasteurized or ultra-pasteurized.

One comment requested that eggnog-flavored milk be standardized. The product is defined in the PMO as containing a minimum of 3.25 percent milkfat and 0.5 percent egg yolk solids.

FDA advises that eggnog-flavored milk is covered by the standard of identity for milk (21 CFR 131.110). Section 131.110(c)(2)(ii) allows the addition of safe and suitable flavors. When added at the 0.5 percent level, egg yolk solids would be considered characterizing flavoring and the name "eggnog-flavored milk" may be declared on the label of the food.

10. *Yogurt, lowfat yogurt, and nonfat yogurt.* Eleven comments favored the three proposed levels of milkfat content. In response to the agency's request for information about the production of "yogurt" with a 3.25 percent milkfat minimum, most of those commenting stated that a preponderance of their production was "lowfat yogurt." However, several companies indicated that they either now market or intend to market a higher fat yogurt. One comment suggested a milkfat minimum of not less than 1.5 percent for "lowfat yogurt." A second comment wanted the term "lowfat" retained as part of the name of the 0.5–2.0 percent milkfat yogurt. Both comments also wanted the percent milkfat declaration provisions deleted because it confuses consumers and does not inform them about the food. Two comments pointed out that adding bulky flavors to yogurts would have the effect of lowering the milkfat and milk solids not fat levels of the entire product. They both requested that allowance be made for lowering the milkfat and milk solids not fat levels in proportion to the quantity of bulky flavoring ingredients added. Bulky flavoring ingredients are said to be added in quantities of up to 25 percent of the weight of the food.

FDA concludes that there is a sufficient amount of "yogurt" containing 3.25 percent milkfat or more being produced in this country to merit establishing the three proposed standards of identity. In addition, the agency advises that it is neither aware of any data, nor were any submitted, that support the requested milkfat minimum of not less than 1.5 percent for lowfat yogurt rather than the proposed level of not less than 0.5 percent. Thus, FDA concludes that this suggestion is without merit and will not provide for it in the regulation for "lowfat yogurt" set forth below. Further, FDA advises that it is not deleting the percent milkfat declaration requirement from the "lowfat yogurt" regulation because a declaration of actual fat content has more meaning to consumers than the term "lowfat" alone for a food that could contain anywhere from 0.5 to 2.0 percent milkfat.

FDA agrees with the comments that adding bulky flavors to yogurts lowers the milkfat and milk solids not fat contents of the resultant food. However, the agency rejects the comments' request to lower the milkfat and milk solids not fat levels in proportion to the quantity of bulky flavors added because there are no recognized methods to separate all of the bulky flavoring material from the yogurts. In addition, there is no method to accurately determine the amount of milkfat and milk solids not fat in every sample of bulky flavored yogurt, lowfat yogurt and nonfat yogurt. Therefore, the only practical way of determining the milkfat and milk solids not fat content of yogurts is to sample the yogurt, lowfat yogurt, or nonfat yogurt at the point of manufacture prior to the time the bulky flavoring material is added. For these reasons, FDA concludes that it will not make specific allowances for added bulky flavors, but will require that yogurt, lowfat yogurt, and nonfat yogurt meet the minimum or maximum requirements for milkfat or milk solids not fat prior to the addition of bulky flavors, as established by the applicable standard of identity. This is consistent with the Codex standard for bulky flavored yogurts.

FDA points out that the two Codex standards for yogurt set forth above provide for different milkfat levels than the U.S. standards set forth below. The Codex standard and the proposed U.S. standard are in accord regarding the milkfat level for nonfat yogurt. The Codex standard provides for "0.5 percent maximum" and the proposed U.S. standard sets the level at "less than 0.5 percent". For lowfat yogurt, the Codex standard provides for "less than 3.0 percent maximum" and the proposed U.S. standard sets the levels at "0.5 percent minimum to 2.0 percent maximum". Finally, for yogurt, the Codex standard provides for "3.0 percent minimum" and the proposed U.S. standard sets the level at "3.25 percent minimum".

FDA believes that the milkfat range provided for in the Codex standards

does not provide a clear delineation between lowfat yogurt and yogurt. Furthermore, the milkfat minima and maxima in the proposed U.S. standards are consistent with the already established milkfat levels used in the marketing of lowfat milk, lowfat dry milk, and lowfat cottage cheese. Therefore, FDA is retaining the milkfat levels as proposed.

Sixty-six comments, including 41 from consumers, were received regarding the proposed provision for "yogurt heat-treated after culturing". Comments, both pro and con, were received from industry, State agencies, academia, and two consumers regarding the use of heat treatment to extend the shelf-life of yogurts. Most of the opposing comments cited the benefits of the live culture microorganisms and maintained that use of the name "yogurt" on a heat-treated product constitutes misrepresentation and fraud to the consumer. Others opposing heat treatment of yogurts asserted that the shelf-life of the nonheat-treated product is sufficient for distribution and consumption. In addition, their comments were of the opinion that there was little, if any, of the heat-treated product now on the market. This was rebutted by a manufacturer who stated that he has been producing and marketing heat-treated yogurt in a large section of the country for 13 years, a process which he maintains establishes the product as yogurt. One opposing comment expressed concern that the enzyme lactase, which aids digestion of lactose in the human intestinal tract, would be destroyed. Many of these comments suggested that heat-treated yogurt be marketed under a fanciful name.

Many comments were received from consumers regarding the proposed labeling requirement for heat-treated yogurt. Most consumer comments received expressed approval of the proposed "heat-treated after culturing" labeling that would be used to differentiate heat-treated from nonheat-treated yogurts. The primary reason consumers gave for favoring the labeling was that they wanted to avoid buying heat-treated yogurts. Many industry comments favored the labeling as proposed, while others suggested alternatives such as "pasteurized after culturing", "dead organisms present", "denatured yogurt", and "heat-treated to inactivate culture". Some of the industry comments assumed that use of the "heat-treated after culturing" phrase applies only to yogurts that have been heat-treated to the point of commercial sterility and not to products that undergo milder heat treatments designed to just reduce the bacterial population or destroy the lactase. The comments assert that this type of heat treatment retards deterioration caused by excessive lactic acid production. One comment maintained that it is discriminatory to require only yogurts, of all the cultured products in the proposal, to bear "heat-treated after culturing" labeling.

FDA concludes that it is in the best interests of both consumers and international trade to permit heat treatment of yogurts and to require auxiliary labeling, as proposed, to inform consumers that the product has been heat-treated. The agency is aware of the controversy surrounding the question of whether "yogurt" must contain live microorganisms. While traditional yogurt contains viable microorganisms, a fact recognized by a substantial number of the consumers who commented, the word "yogurt" also describes a particular food to a large number of consumers who may be unaware of the presence of viable bacteria. FDA does not agree that allowing heat-treated products to be sold under the name "yogurt" is misleading to consumers as long as the name is accompanied by auxiliary labeling to distinguish heat-treated from nonheat-treated yogurts. After considering the suggested alternatives to the proposed phrase "heat-treated after culturing", the agency concludes that the suggested alternatives do not provide any more complete information than that which was proposed. Furthermore, the proposed phrase is consistent with terminology contained in the Codex standard for flavored yogurts.

FDA advises that, in regard to the inactivation of lactase by the heat treatment process, it is aware of research being done on the role of lactase from the bacterial cells in yogurts in digestion of lactose in the gastrointestinal tract of lactose-intolerant individuals. However, FDA believes that substantial experimentation is still required to clearly establish the value of bacterial lactase in vivo. FDA also advises that the "heat-treated after culturing" phrase must be used when any heat is applied to yogurts after completion of the culturing process, whatever the purpose. The purpose of the phrase "heat-treated after culturing" is to alert consumers that the food has been subjected to a heat treatment after culturing. Such treatment may cause partial or complete loss of volatile flavors and destruction of some or all of the enzymes and culture microorganisms. Regarding the assertion that "heat-treated after culturing" labeling for yogurts is discriminatory, FDA points out that heat treatment after culturing was proposed only in the yogurt standards. Therefore, auxiliary labeling is required only for these foods. FDA did not propose providing for heat treatment after culturing for the other cultured milk products, nor were any comments received to indicate that such a provision was needed. Consequently, the labeling statement "heat-treated after culturing" does not apply to these products.

A number of comments suggested that a separate standard of identity should be established for frozen yogurt because frozen yogurt and yogurt are too dissimilar in composition and form to be included in one standard of identity. One comment included a suggested standard for the frozen forms of these products. One comment suggested that if a separate standard is not established, the yogurt standard should be modified to provide for the manufacture of frozen forms of these yogurts.

FDA agrees that a separate standard for frozen yogurts may be warranted. The frozen forms of these foods are too dissimilar to be covered by the same standards of identity for the nonfrozen forms because of the process of manufacture and the resultant physical attributes. However, it is inappropriate to establish such a standard at this stage of the rulemaking procedure. The agency invites any interested person to submit a petition consistent with the requirements of 21 CFR 10.30 proposing standards of identity for the frozen or semifrozen forms of nonfat yogurt, lowfat yogurt, and yogurt. In the meantime, such foods are considered nonstandardized foods and may be sold under the name "frozen yogurt", "frozen lowfat yogurt", or "frozen nonfat yogurt", and must be further labeled in accordance with 21 CFR Part 101.

One comment pointed out that the normal titratable acidity for yogurt is 1.0–1.15 percent, expressed as lactic acid. Therefore, a minimum titratable acidity of 0.9 percent for all the standards would be more reasonable than the 0.5 percent level set in the proposed standards. A comment was also received regarding the titratable acidity of frozen yogurt. This comment stated that a titratable acidity of 0.5 percent would adversely affect their nonfruited varieties of frozen yogurt and suggested a titratable acidity of 0.35 percent for these frozen yogurts.

FDA agrees with the first comment and the appropriate changes have been made in paragraph (a) of §§ 131.200, 131.203, and 131.206, as set forth below. The comment on the titratable acidity of

frozen yogurts is not applicable to these standards because the proposed standards of identity for yogurts will not cover frozen forms of yogurt. This point will be considered, however, if a petition to establish a standard of identity is received in the future.

Two comments favored direct addition of preservatives to yogurts because the low pH of yogurts favors the growth of yeasts and molds which shortens the shelf life of the product. They indicated that some manufacturers already put small amounts of sorbates into their yogurts to extend their shelf lives. One of the comments pointed out that preservatives added by way of flavoring ingredients are allowed by the Codex standard for flavored yogurts (A-11(b)). Therefore, it seems reasonable to allow the direct addition of preservatives to yogurts.

FDA does not agree with the reasoning of the last comment. Any preservatives added to flavoring ingredients would be present only in sufficient quantity to perform their function in the flavoring. When added to yogurts, this quantity of preservative would probably not be sufficient to have a preserving effect in the yogurts. No data were submitted to indicate that preservatives would not have an adverse effect on the characterizing bacteria nor to support the contention that there is a need for the use of preservatives in yogurts. Therefore, FDA concludes that no justification has been provided for the use of preservatives as optional ingredients in any of these foods. The agency invites interested persons who believe that a need for preservatives exists, to submit a petition to amend the standards. The petition should provide data supporting the need for preservatives and demonstrating that their use would not be detrimental to the characterizing bacteria and would promote honesty and fair dealing in the interest of consumers.

One comment requested limiting the quantity of flavoring ingredient that may be used in yogurts to 25 percent, by weight, of the finished food. Two comments requested deletion of the term "characterizing flavoring ingredients" because the term too narrowly restricts the flavors that may properly be used in yogurt. Thus, a combination of flavors, none of which singly provide the characterizing flavor of the yogurt, may be used.

FDA believes the cost of flavoring ingredients, as well as organoleptic factors, make their use self-limiting and, that restricting their use is not necessary. FDA agrees with the latter two comments because it never intended to limit the type or source of flavoring ingredients that may be used in yogurts. Therefore, the word "characterizing" (due to interpretation of § 101.22(i)) is being deleted from paragraph (c)(3) of §§ 131.200, 131.203, and 131.206, as set forth below.

Two comments requested that the standards provide for yogurts prepared by direct acidification. One comment stated that such a product is on the market and enjoying consumer acceptance. The comments pointed out that a provision for foods prepared in this manner has precedent in the standards for "acidified sour cream" and "directly set cottage cheese".

FDA points out that the name "yogurt" traditionally belongs to a food containing the characterizing microorganisms *Lactobacillus bulgaricus* and *Streptococcus thermophilus* and possessing the flavor and aroma profiles, enzymes, and lactic acid created by these microorganisms. An acidified yogurt product would fall under the provisions of the acidified milk standards of identity, if in fact the flavor-, aroma-, and enzyme-producing organisms were present in the food. Therefore, FDA concludes that a separate standard of identity for acidified yogurt is not warranted.

One manufacturer stated that the proposed standards for yogurts will unreasonably interfere with the marketing of shelf-stable, bottled dressings for salads of various types such as "Italian", "Blue cheese", and "Thousand Island". The manufacturer claims these products contain 15 percent, by weight, of reconstituted nonfat yogurt (which is equivalent to 1.31 percent nonfat yogurt solids). They are concerned that the proposed standards of identity may: (1) be interpreted to apply to their products; (2) indirectly prohibit them from using yogurt as an ingredient in their dressings and the name "yogurt" as part of the name of their dressings; and (3) require them to include the phrase "heat-treated after culturing" as part of the name of their dressings. A suggested standard of identity for pourable dressings made with yogurt was submitted as part of the comment.

FDA sees no need to establish a standard of identity for pourable dressings containing nonfat yogurt, lowfat yogurt, or yogurt. The proposed standards of identity for yogurts will not interfere with the marketing of correctly labeled pourable dressings which utilize one of the three types of yogurt as an ingredient in the food. The standards of identity would not apply to a pourable dressing made with any one of the three types of yogurt as an ingredient, but they would apply to the type of yogurt used as an ingredient. Thus, if nonfat yogurt is used in the pourable dressing, it must comply with the requirements of the standard for nonfat yogurt and be declared as "nonfat yogurt" in the ingredient statement. Likewise, if reconstituted nonfat yogurt is used, it must be declared as "reconstituted nonfat yogurt". Standards of identity for a food do not preclude the use of that food as an ingredient in another food. To use the name "yogurt", "lowfat yogurt", or "nonfat yogurt" as part of the name of these dressings, the declared type of yogurt used must be in a sufficient quantity to characterize the dressing. It is questionable whether it is possible to characterize this manufacturer's dressings with nonfat yogurt since the amount of reconstituted nonfat yogurt used in the pourable dressings is relatively small. Furthermore, the spices and other flavors used to create the different types of dressings, e.g., "Italian reconstituted nonfat yogurt dressing", would probably mask the flavor of the reconstituted nonfat yogurt, and spices and other flavor ingredients would actually provide the flavor that characterizes the dressing. It is doubtful that there is sufficient nonfat yogurt in the dressings to have a physical effect on their consistency. If the dressings do contain a significant quantity of nonfat yogurt solids, there is nothing to prevent the manufacturer from making a factual statement on the label that the product contains reconstituted nonfat yogurt.

One comment requested that the term "milk solids not fat" be replaced with "solids not fat" in the standards for yogurts. Thus, solids, other than milk-derived solids, that maintain the protein quantity and quality levels provides for in the standards could be used, e.g., isolated soy protein. The comment stated that this action, along with changing the 8.25 percent milk solids not fat level to an 8.25 percent solids not fat level, would make these standards consistent with FDA's "safe and suitable" policy. The comment also stated that "industry and consumers view the product name 'yogurt' as a means of identifying the basic physical and organoleptic nature of the product and not as a means to restrict the exact compositional nature."

FDA disagrees with the comment's perception of how industry and consumers view yogurt. "Yogurt" has a well-established historical identity gained over the period of hundreds of years of manufacture and consumption in various parts of the world. Consumers expect yogurt to be a fresh dairy product composed primarily of dairy ingredients.

A "yogurt-like" product containing isolated soy protein, or any other ingredient which replaces the milk components normally found in yogurt, would be a substitute product made in semblance of yogurt and must be labeled as either a "substitute" or an "imitation", in accordance with 21 CFR 101.3(e). Substitution of nondairy ingredients for normally expected dairy ingredients is not suitable in these products. Therefore, FDA concludes that the requested changes would not be consistent with the agency's "safe and suitable" policy and would not be in the best interests of consumers.

One comment asked whether the bacteria *Lactobacillus acidophilus* would be permitted in the manufacture of yogurt.

FDA concludes that *Lactobacillus acidophilus* may be used, as can any other lactic-acid producing bacteria, but only in addition to the *Lactobacillus bulgaricus* and *Streptococcus thermophilus* cultures that characterize the food.

One comment suggested that the yogurt standards should provide nomenclature for other physical forms of yogurt such as "yogurt drink" for the liquid form.

FDA recognizes that yogurts in the liquid form are valid forms of yogurt. However, it is not necessary to provide for this type of labeling in the standards because label regulations found in 21 CFR 101.3(c) provide sufficient guidelines for the use of terms describing the physical form of a food. Therefore, FDA concludes that this type of nomenclature need not be provided for in the individual yogurt standards.

One comment requested that the alternative spelling "yogourt" be provided for in the standards of identity for yogurts. The comment explained that the prefix "yogo" is a registered trademark of the company and that they have been utilizing the spelling "yogourt" on their product for almost 30 years. They believe it would cause an unreasonable hardship to change the spelling because consumers have come to identify it with their brand.

FDA rejects this requested change. The agency believes that "yogurt" is the more commonly accepted spelling of the name of these products and any other spelling of the standardized name would be confusing, and possibly misleading to the consumer. However, the agency advises that the fanciful name "yogourt" may be used, where appropriate, but the word "yogurt" must appear on the label as part of the name of yogurt, lowfat yogurt, and nonfat yogurt.

One comment thought that the word "yogurt" should be printed in larger size type than the words "lowfat" or "nonfat" thus giving emphasis to the word "yogurt". The comment maintained that on a package where the lid is the principal display panel, such as a yogurt container, the smaller type size for the words "lowfat" and "nonfat" is necessary.

FDA points out that the full names of the foods are "lowfat yogurt" and "nonfat yogurt". Hence, it is reasonable to expect the entire name of the food to be in the same size type. This is consistent with the requirements of other milk and cream standards of identity, such as for "lowfat milk". The size of the package has no bearing on this requirement. Therefore, the requested change is not being made.

One comment expressed the opinion that it was unfair that lowfat and nonfat yogurts must have nutrition labeling while it is not required for the higher fat content yogurt. This comment suggested that nutrition labeling be required for all yogurts.

FDA advises that, in accordance with 21 CFR 101.9, nutrition labeling is required when any nutrition claim such as "nonfat", "lowfat", or the percent milkfat declaration required on lowfat products is used on the label of a food. The agency has no authority to require nutrition labeling on a food when neither nutrients are added nor nutrition claims are being made about the food. Therefore, FDA cannot require nutrition labeling for "yogurt" except when a nutrition claim is made.

One comment requested that the percent milk solids added to yogurts be declared on the label to provide more information for lactose-intolerant consumers.

FDA advises that a "percent milk solids added" declaration will not impart information about the lactose content of yogurts for several reasons. First, the milk solids content includes all solids obtained from milk, i.e., milkfat and nonfat milk solids. Second, the nonfat milk solids fraction is made up of several compounds of which lactose is only one. Third, much of the lactose component is broken down to glucose and galactose by the lactic acid-producing bacteria during the culturing process. These simple sugars are easily digestible by lactose-intolerant consumers. The FDA concludes that such a declaration would not inform consumers about the lactose content of yogurts and, therefore, has not included this requirement in the regulations set forth below.

One comment thought it necessary to differentiate between natural yogurt and yogurt made with stabilizers and other such ingredients. No suggested label statements were submitted.

FDA points out that full ingredient labeling will adequately inform consumers of all the ingredients used in yogurts, thus making informed choices easier.

Several consumers wanted the "make-procedure" noted on the label of yogurts.

FDA assumes that by "make-procedure" these comments refer to whether or not yogurts have been heat treated after culturing. FDA concludes that the requirement that the phrase "heat treated after culturing" appear on the label of foods which have been so processed adequately informs consumers of the "make-procedure" which was used.

11. *Characterizing flavoring ingredients.* FDA advises that it is deleting the word "characterizing" as a descriptor for the optional ingredient "characterizing flavoring ingredients" from paragraph (e)(3) of §§ 131.111 *Acidified milk;* 131.136 *Acidified lowfat milk;* 131.144 *Acidified skim milk;* and 131.170 *Eggnog;* and from paragraph (d)(3) of §§ 131.112 *Cultured milk;* 131.138 *Cultured lowfat milk;* and 131.146 *Cultured skim milk,* to be consistent with the change to the yogurt standards discussed earlier in this document.

The document published in the **Federal Register** of June 10, 1977, proposed the use of "safe and suitable" nutritive carbohydrate sweeteners and acids. However, based on information resulting from a series of public hearings held between August 1978 and October 1978, it appears that consumers want in food standards a specific listing, by name, of those ingredients which characterize the food rather than simply a general provision for the use of "safe and suitable" ingredients. A notice requesting public comment on a tentative proposed revision of the agency's policy regarding the use of "safe and suitable" provisions in food standards was published in the **Federal Register** of December 21, 1979 (44 FR 75990). Consistant with consumer request, FDA, therefore, is listing in the final regulations set forth below, the suitable nutritive carbohydrate sweeteners and acids that may be used. The agency requests comments concerning the completeness of the list. If any commonly used nutritive carbohydrate sweeteners have been omitted, they will be included in the regulation at the time a notice confirming the effective date of the final regulation is published. Comments should be submitted to the Dockets Management Branch, Food and Drug

Administration (address above), during the period for objections.

After considering the comments received, FDA concludes that it will promote honesty and fair dealing in the interests of consumers to establish standards of identity for the foods discussed above, as set forth below.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 401, 701(e), 52 Stat. 1046 as amended, 70 Stat. 919 as amended (21 U.S.C. 341, 371(e))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), Part 131 is amended by (1) redesignating § 131.145 *Skim milk* as § 131.143 *Skim milk*, and (2) adding §§ 131.111, 131.112, 131.136, 131.138, 131.144, 131.146, 131.170, 131.200, 131.203, and 131.206 to read as follows:

§ 131.111 Acidified milk.

(a) *Description.* Acidified milk is the food produced by souring one or more of the optional dairy ingredients specified in pargaph (c) of this section with one or more of the acidifying ingredients specified in paragraph (d) of this section, with or without the addition of characterizing microbial organisms. One or more of the other optional ingredients specified in paragraphs (b) and (e) of this section may also be added. When one or more of the ingredients specified in paragraph (e)(1) of this section are used, they shall be included in the souring process. All ingredients used are safe and suitable. Acidified milk contains not less than 3.25 percent milkfat and not less than 8.25 percent milk solids not fat and has a titratable acidity of not less than 0.5 percent, expressed as lactic acid. The food may be homogenized and shall be pasteurized or ultra-pasteurized prior to the addition of the microbial culture and, when applicable, the addition of flakes or granules of butterfat or milkfat.

(b) *Vitamin addition (optional).* (1) If added, vitamin A shall be present in such quantity that each 946 milliliters (quart) of the food contains not less than 2,000 International Units thereof, within limits of good manufacturing practice.

(2) If added, vitamin D shall be present in such quantity that each 946 milliliters (quart) of the food contains 400 International Units thereof, within limits of good manufacturing practice.

(c) *Optional dairy ingredients.* Cream, milk, partially skimmed milk, or skim milk, used alone or in combination.

(d) *Optional acidifying ingredients.* Adipic acid, citric acid, fumaric acid, glucono-*delta*-lactone, hydrochloric acid, lactic acid, malic acid, phosphoric acid, succinic acid, and tartaric acid.

(e) *Other optional ingredients.* (1) Concentrated skim milk, nonfat dry milk, buttermilk, whey, lactose, lactalbumins, lactoglobulins, or whey modified by partial or complete removal of lactose and/or minerals, to increase the nonfat solids content of the food: *Provided*, That the ratio of protein to total nonfat solids of the food, and the protein efficiency ratio of all protein present, shall not be decreased as a result of adding such ingredients.

(2) Nutritive carbohydrate sweeteners. Sugar (sucrose), beet or cane; invert sugar (in paste or sirup form); brown sugar; refiner's sirup; molasses (other than blackstrap); high fructose corn sirup; fructose; fructose sirup; maltose; maltose sirup, dried maltose sirup; malt extract, dried malt extract; malt sirup, dried malt sirup; honey; maple sugar; or any of the sweeteners listed in Part 168 of this chapter, except table sirup.

(3) Flavoring ingredients.

(4) Color additives that do not impart a color simulalting that of milkfat or butterfat.

(5) Stabilizers.

(6) Butterfat or milkfat, in the form of flakes or granules.

(7) Aroma- and flavor-producing microbial culture.

(8) Salt.

(9) Citric acid, in a maximum amount of 0.15 percent by weight of the milk used, or an equivalent amount of sodium citrate, as a flavor precursor.

(f) *Methods of analysis.* The following referenced methods of analysis are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th ed., 1980,[1] which is incorporated by reference.

(1) Milkfat content—As determined by the method prescribed in section 16.059, "Roese-Gottlieb Method (Reference Method) (11)—Official Final Action," under the heading "Fat."

(2) Milk solids not fat content—Calculated by subtracting the milkfat content from the total solids content as determined by the method prescribed in section 16.032, "Method I—Official Final Action," under the heading "Total Solids."

(3) Titratable acidity—As determined by the method prescribed in section 16.023, "Acidity (2)—Official Final Action," or by an equivalent potentiometric method.

(g) *Nomenclature.* The name of the food is "acidified milk". The full name of the food shall appear on the principal display panel of the label in type of uniform size, style, and color. The name of the food shall be accompanied by a declaration indicating the presence of any characterizing flavoring as specified in § 101.22 of this chapter, and may be accompanied by a declaration such as a traditional name of the food or the generic name of the organisms used, thereby indicating the presence of the characterizing microbial organisms or ingredients when used, e.g., "acidified kefir milk", "acidified acidophilus milk", or when characterizing ingredients such as those in paragraph (e) (6), (7), (8), and (9) of this section are used, the food may be named "acidified buttermilk".

(1) The following terms shall accompany the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half of the height of the letters used in such name:

(i) The phrase "vitamin A" or "vitamin A added", or "vitamin D" or "vitamin D added", or "vitamins A and D added", as appropriate. The word "vitamin" may be abbreviated "vit.".

(ii) The word "sweetened" if nutritive carbohydrate sweetener is added without the addition of characterizing flavoring.

(2) The term "homogenized" may appear on the label if the dairy ingredients used are homogenized.

(h) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

§ 131.112 Cultured milk.

(a) *Description.* Cultured milk is the food produced by culturing one or more of the optional dairy ingredients specified in paragraph (c) of this section with characterizing microbial organisms. One or more of the other optional ingredients specified in paragraphs (b) and (d) of this section may also be added. When one or more of the ingredients specified in paragraph (d)(1) of this section are used, they shall be included in the culturing process. All ingredients used are safe and suitable. Cultured milk contains not less than 3.25 percent milkfat and not less than 8.25 percent milk solids not fat and has a titratable acidity of not less than 0.5 percent, expressed as lactic acid. The food may be homogenized and shall be pasteurized or ultra-pasteurized prior to the addition to the microbial culture, and when applicable, the addition of flakes or granules of butterfat or milkfat.

(b) *Vitamin addition (optional).* (1) If added, vitamin A shall be present in such quantity that each 946 milliliters (quart) of the food contains not less than 2,000 International Units thereof, within limits of good manufacturing practice.

[1] Copies may be obtained from: Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044, or examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(2) If added, vitamin D shall be present in such quantity that each 946 milliliters (quart) of the food contains 400 International Units thereof, within limits of good manufacturing practice.

(c) *Optional dairy ingredients.* Cream, milk, partially skimmed milk, or skim milk, used alone or in combination.

(d) *Other optional ingredients.* (1) Concentrated skim milk, nonfat dry milk, buttermilk, whey, lactose, lactalbumins, lactoglobulins, or whey modified by partial or complete removal of lactose and/or minerals, to increase the nonfat solids content of the food: *Provided,* That the ratio of protein to total nonfat solids of the food, and the protein efficiency ratio of all protein present, shall not be decreased as a result of adding such ingredients.

(2) Nutritive carbohydrate sweeteners. Sugar (sucrose), beet or cane; invert sugar (in paste or sirup form); brown sugar; refiner's sirup; molasses (other than blackstrap); high fructose corn sirup; fructose; fructose sirup; maltose; maltose sirup, dried maltose sirup; malt extract, dried malt extract; malt sirup, dried malt sirup; honey; maple sugar; or any of the sweeteners listed in Part 168 of this chapter, except table sirup.

(3) Flavoring ingredients.

(4) Color additives that do not impart a color simulating that of milkfat or butterfat.

(5) Stabilizers.

(6) Butterfat or milkfat, in the form of flakes or granules.

(7) Aroma- and flavor-producing microbial culture.

(8) Salt.

(9) Citric acid, in a maximum amount of 0.15 percent by weight of the milk used, or an equivalent amount of sodium citrate, as a flavor precursor.

(e) *Methods of analysis.* The following referenced methods of analysis are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th ed., 1980,[1] which is incorporated by reference.

(1) Milkfat content—section 16.059, "Roese-Gottlieb Method (Reference Method) (11)—Official Final Action," under the heading "Fat."

(2) Milk solids not fat content—Calculated by subtracting the milkfat content from the total solids content as determined by the method prescribed in section 16.032, "Method I—Official Final Action," under the heading "Total Solids."

(3) Titratable acidity—As determined by the methods prescribed in section 16.023 "Acidity (2)—Official Final Action," or by an equivalent potentiometric method.

(f) *Nomenclature.* The name of the food is "cultured milk". The full name of the food shall appear on the principal display panel in type of uniform size, style, and color. The name of the food shall be accompanied by a declaration indicating the presence of any characterizing flavoring as specified in § 101.22 of this chapter, and may be accompanied by a declaration such as a traditional name of the food or the generic name of the organisms used, thereby indicating the presence of the characterizing microbial organisms or ingredients, e.g., "kefir cultured milk", "acidophilus cultured milk", or when characterizing ingredients such as those in paragraph (d) (6), (7), (8), and (9) of this section, and lactic acid-producing organisms are used the food may be named "cultured buttermilk".

(1) The following terms shall accompany the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half of the height of the letters used in such name:

(i) The phrase "vitamin A" or "vitamin A added", or "vitamin D" or "vitamin D added", or "vitamin A and D added", as appropriate. The word "vitamin" may be abbreviated "vit.".

(ii) The word "sweetened" if nutritive carbohydrate sweetener is added without the addition of characterizing flavoring.

(2) The term "homogenized" may appear on the label if the dairy ingredients used are homogenized.

(g) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

§ 131.136 Acidified lowfat milk.

(a) *Description.* Acidified lowfat milk is the food produced by souring one or more of the optional dairy ingredients specified in paragraph (c) of this section with one or more of the acidifying ingredients specified in paragraph (d) of this section, with or without the addition of characterizing microbial organisms. One or more of the other optional ingredients specified in paragraphs (b) and (e) of this section may also be added. When one or more of the ingredients specified in paragraph (e)(1) of this section are used, they shall be included in the souring process. All ingredients used are safe and suitable. Acidified lowfat milk contains not less than 0.5 percent nor more than 2.0 percent milkfat and not less than 8.25 percent milk solids not fat and has a titratable acidity of not less than 0.5 percent, expressed as lactic acid. The food may be homogenized and shall be pasteurized or ultra-pasteurized prior to the addition of the microbial culture and, when applicable, the addition of flakes or granules of butterfat or milkfat.

(b) *Vitamin addition (optional).* (1) If added, vitamin A shall be present in such quantity that each 946 milliliters (quart) of the food contains not less than 2,000 International Units thereof, within limits of good manufacturing practice.

(2) If added, vitamin D shall be present in such quantity that each 946 milliliters (quart) of the food contains 400 International Units thereof, within limits of good manufacturing practice.

(c) *Optional dairy ingredients.* Cream, milk, partially skimmed milk, or skim milk, used alone or in combination.

(d) *Optional acidifying ingredients.* Adipic acid, citric acid, fumaric acid, glucono-*delta*-lactone, hydrochloric acid, lactic acid, malic acid, phosphoric acid, succinic acid, and tartaric acid.

(e) *Other optional ingredients.* (1) Concentrated skim milk, nonfat dry milk, buttermilk, whey, lactose, lactalbumins, lactoglobulins, or whey modified by partial or complete removal of lactose and/or minerals, to increase the nonfat solids content of the food: *Provided,* That the ratio of protein to total nonfat solids of the food, and the protein efficiency ratio of all protein present, shall not be decreased as a result of adding such ingredients.

(2) Nutritive carbohydrate sweeteners. Sugar (sucrose), beet or cane; invert sugar (in paste or sirup form); brown sugar; refiner's sirup; molasses (other than blackstrap); high fructose corn sirup; fructose; fructose sirup; maltose; maltose sirup, dried maltose sirup; malt extract, dried malt extract; malt sirup, dried malt sirup; honey; maple sugar; or any of the sweeteners listed in Part 168 of this chapter, except table sirup.

(3) Flavoring ingredients.

(4) Color additives that do not impart a color simulating that of milkfat or butterfat.

(5) Stabilizers.

(6) Butterfat or milkfat in the form of flakes or granules.

(7) Aroma- and flavor-producing microbial culture.

(8) Salt.

(9) Citric acid, in a maximum amount of 0.15 percent by weight of the dairy ingredients used, or an equivalent amount of sodium citrate, as a flavor precursor.

(f) *Methods of analysis.* The following referenced methods of analysis are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th ed., 1980,[1] which is incorporated by reference.

(1) Milkfat content—As determined by the method prescribed in section 16.059, "Roese-Gottlieb Method (Reference

Method) (11)—Official Final Action," under the heading "Fat."

(2) Milk solids not fat content—Calculated by subtracting the milkfat content from the total solids content as determined by the method prescribed in section 16.032, "Method I—Official Final Action," under the heading "Total Solids."

(3) Titratable acidity—As determined by the method prescribed in section 16.023, "Acidity (2)—Official Final Action," or by an equivalent potentiometric method.

(g) *Nomenclature.* The name of the food is "acidified lowfat milk". The full name of the food shall appear on the principal display panel of the label in type of uniform size, style, and color. The name of the food shall be accompanied by a declaration indicating the presence of any characterizing flavoring as specified in § 101.22 of this chapter, and may be accompanied by a declaration such as a traditional name of the food or the generic name of the organisms used, thereby indicating the presence of the characterizing microbial organisms or ingredients when used, e.g., "acidified kefir lowfat milk", "acidified acidophilus lowfat milk", or when characterizing ingredients such as those in paragraph (e)(6), (7), (8), and (9) of this section are used, the food may be named "acidified lowfat buttermilk".

(1) The following terms shall accompany the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half of the height of the letters used in such name:

(i) The phrase "—— percent milkfat", the blank to be filled in with the fraction ½ or multiple thereof closest to the actual fat content of the food.

(ii) The word "sweetened" if nutritive carbohydrate sweetener is added without the addition of characterizing flavoring.

(iii) The phrase "vitamin A" or "vitamin A added", or "vitamin D" or "vitamin D added", or "vitamins A and D added", as appropriate. The word "vitamin" may be abbreviated "vit.".

(2) The term "homogenized" may appear on the label if the dairy ingredients used are homogenized.

(h) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

§ 131.138 Cultured lowfat milk.

(a) *Description.* Cultured lowfat milk is the food produced by culturing one or more of the optional dairy ingredients specified in paragraph (c) of this section with characterizing microbial organisms. One or more of the other optional ingredients specified in paragraphs (b) and (d) of this section may also be added. When one or more of the ingredients specified in paragraph (d)(1) of this section are used, they shall be included in the culturing process. All ingredients used are safe and suitable. Cultured lowfat milk contains not less than 0.5 percent nor more than 2 percent milkfat and not less than 8.25 percent milk solids not fat and has a titratable acidity of not less than 0.5 percent, expressed as lactic acid. The food may be homogenized and shall be pasteurized or ultra-pasteurized prior to the addition of the microbial culture and, when applicable, the addition of flakes or granules of butterfat or milkfat.

(b) *Vitamin addition (optional).* (1) If added, vitamin A shall be present in such quantity that each 946 milliliters (quart) of the food contains not less than 2,000 International Units thereof, within limits of good manufacturing practice.

(2) If added, vitamin D shall be present in such quantity that each 946 milliliters (quart) of the food contains 400 International Units thereof, within limits of good manufacturing practice.

(c) *Optional dairy ingredients.* Cream, milk, partially skimmed milk, or skim milk, used alone or in combination.

(d) *Other optional ingredients.* (1) Concentrated skim milk, nonfat dry milk, buttermilk, whey, lactose, lactalbumins, lactoglobulins, or whey modified by partial or complete removal of lactose and/or minerals, to increase the nonfat solids content of the food: *Provided,* That the ratio of protein to total nonfat solids of the food, and the protein efficiency ratio of all protein present shall not be decreased as a result of adding such ingredients.

(2) Nutritive carbohydrate sweeteners. Sugar (sucrose), beet or cane; invert sugar (in paste or sirup form); brown sugar; refiner's sirup; molasses (other than blackstrap); high fructose corn sirup; fructose; fructose sirup; maltose; maltose sirup, dried maltose sirup; malt extract, dried malt extract; malt sirup, dried malt sirup; honey; maple sugar; or any of the sweeteners listed in Part 168 of this chapter, except table sirup.

(3) Flavoring ingredients.

(4) Color additives that do not impart a color simulating that of milkfat or butterfat.

(5) Stabilizers.

(6) Butterfat or milkfat, in the form of flakes or granules.

(7) Aroma- and flavor-producing microbial culture.

(8) Salt.

(9) Citric acid, in a maximum amount of 0.15 percent by weight of the milk used, or an equivalent amount of sodium citrate, as a flavor precursor.

(e) *Methods of analysis.* The following referenced methods of analysis are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th ed., 1980,[1] which is incorporated by reference.

(1) Milkfat content—As determined by the method prescribed in section 16.059, "Roese-Gottlieb Method (Reference Method) (11)—Official Final Action," under the heading "Fat."

(2) Milk solids not fat content—Calculated by subtracting the milkfat content from the total solids content as determined by the method prescribed in section 16.032, "Method I—Official Final Action," under the heading "Total Solids."

(3) Titratable acidity—As determined by the method prescribed in section 16.023, "Acidity (2)—Official Final Action," or by an equivalent potentiometric method.

(f) *Nomenclature.* The name of the food is "cultured lowfat milk." The full name of the food shall appear on the principal display panel of the label in type of uniform size, style, and color. The name of the food shall be accompanied by a declaration indicating the presence of any characterizing flavoring as specified in § 101.22 of this chapter, and may be accompanied by a declaration such as a traditional name of the food or the generic name of the organisms used, thereby indicating the presence of the characterizing microbial organisms or ingredients, e.g., "kefir cultured lowfat milk", "acidophilus cultured lowfat milk," or when characterizing ingredients such as those in paragraph (d)(6), (7), (8) and (9) of this section, and lactic acid-producing organisms are used the food may be named "cultured lowfat buttermilk".

(1) The following terms shall accompany the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half of the height of the letters used in such name:

(i) The phrase "vitamin A" or "vitamin A added," or "vitamin D" or "vitamin D added", or "vitamins A and D added", as appropriate. The word "vitamin" may be abbreviated "vit.".

(ii) The phrase "— percent milkfat", the blank to be filled in with the fraction ½ or multiple thereof closest to the actual fat content of the food.

(iii) The word "sweetened" if nutritive carbohydrate sweetner is added without the addition of characterizing flavoring.

(2) The term "homogenized" may appear on the label if the dairy ingredients used are homogenized.

(g) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

§ 131.144 Acidified skim milk.

(a) *Description.* Acidified skim milk is the food produced by souring one or more of the optional dairy ingredients specified in paragraph (c) of this section with one or more of the acidifying ingredients specified in paragraph (d) of this section, with or without the addition of characterizing microbial organisms. One or more of the other opitonal ingredients specified in paragraphs (b) and (e) of this section may also be added. When one or more of the ingredients specified in paragraph (e)(1) of this section are used, they shall be included in the souring process. All ingredients used are safe and suitable. Acidified skim milk contains less than 0.5 percent milkfat and not less than 8.25 percent milk solids not fat and has a titratable acidity of not less than 0.5 percent, expressed as lactic acid. The food may be homogenized and shall be pasteurized or ultra-pasteurized prior to the addition of the microbial culture and when applicable, the addition of flakes or granules of butterfat or milkfat.

(b) *Vitamin addition (optional).* (1) If added, vitamin A shall be present in such quantity that each 946 milliliters (quart) of the food contains not less than 2,000 International Units thereof, within limits of good manufacturing practice.

(2) If added, vitamin D shall be present in such quantity that each 946 milliliters (quart) of the food contains 400 International Units thereof, within limits of good manufacturing practice.

(c) *Optional dairy ingredients.* Cream, milk, partially skimmed milk, or skim milk, used alone or in combination.

(d) *Optional acidifying ingredients.* Adipic acid, citric acid, fumaric acid, glucono-*delta*-lactone, hydrochloric acid, lactic acid, malic acid, phosphoric acid, succinic acid, and tartaric acid.

(e) *Other optional ingredients.* (1) Concentrated skim milk, nonfat dry milk, buttermilk, whey, lactose, lactalbumins, lactoglobulins, or whey modified by partial or complete removal of lactose and/or minerals, to increase the nonfat solids content of the food: *Provided*, That the ratio of protein to total nonfat solids of the food, and the protein efficiency ratio of all protein present, shall not be decreased as a result of adding such ingredients.

(2) Nutritive carbohydrate sweeteners. Sugar (sucrose), beet or cane; invert sugar (in paste or sirup form); brown sugar; refiner's sirup; molasses (other than blackstrap); high fructose corn sirup; fructose; fructose sirup; maltose; maltose sirup, dried maltose sirup; malt extract, dried malt extract; malt sirup, dried malt sirup; honey; maple sugar; or any of the sweetners listed in Part 168 of this chapter, except table sirup.

(3) Flavoring ingredients.

(4) Color additives that do not impart a color simulating that of milkfat or butterfat.

(5) Stabilizers.

(6) Butterfat or milkfat in the form of flakes or granules.

(7) Aroma- and flavor-producing microbial culture.

(8) Salt.

(9) Citric acid, in a maximum amount of 0.15 percent by weight of the dairy ingredients used, or an equivalent amount of sodium citrate, as a flavor precursor.

(f) *Methods of analysis.* The following referenced methods of analysis are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th ed., 1980,[1] which is incorporated by reference.

(1) Milkfat content—As determined by the method prescribed in section 16.059, "Roese-Gottlieb Method (Reference Method) (11)—Official Final Action," under the heading "Fat."

(2) Milk solids not fat content—Calculated by subtracting the milkfat content from the total solids conttent as determined by the method prescribed in section 16.032, "Method I—Official Final Action," under the heading "Total Solids."

(3) Titratable acidity—As determined by the method prescribed in section 16.023, "Acidity (2)—Official Final Action," or by an equivalent potentiometric method.

(g) *Nomenclature.* The name of the food is "acidified skim milk" or alternatively, "acidified nonfat milk". The full name of the food shall appear on the principal display panel of the food in type of uniform size, style and color. The name of the food shall be accompanied by a declaration indicating the presence of any characterizing flavoring as specified in § 101.22 of this chapter, and may be accompanied by a declaration such as a traditional name of the food or the generic name of the organisms used, thereby indicating the presence of the characterizing microbial organisms or ingredients when used, e.g., "acidified kefir skim milk", "acidified acidophilus skim milk", or when characterizing ingredients such as those in paragraph (e)(6), (7), (8), and (9) of this section are used, the food may be named "acidified skim milk buttermilk" or alternatively "acidified nonfat buttermilk".

(1) The following terms shall accompany the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half of the height of the letters used in such name:

(i) The phrase "vitamin A" or "vitamin A added", or "vitamin D" or "vitamin D added", or "vitamins A and D added", as appropriate. The word "vitamin" may be abbreviated "vit.".

(ii) The word "sweetened" if nutritive carbohydrate sweetener is added without the addition of characterizing flavoring.

(2) The term "homogenized" may appear on the label if the dairy ingredients used are homogenized.

(h) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

§ 131.146 Cultured skim milk.

(a) *Description.* Cultured skim milk is the food produced by culturing one or more of the optional dairy ingredients specified in paragraph (c) of this section with characterizing microbial organisms. One or more of the other optional ingredients specified in paragraphs (b) and (d) of this section may also be added. When one or more of the ingredients specified in paragraph (d)(1) of this section are used, they shall be included in the culturing process. All ingredients used are safe and suitable. Cultured skim milk contains less than 0.5 percent milkfat and not less than 8.25 percent milk solids not fat and has a titratable acidity of not less than 0.5 percent, expressed as lactic acid. The food may be homogenized and shall be pasterurized or ultra-pasterurized prior to the addition of the microbial culture and, when applicable, the addition of flakes or granules of butterfat or milkfat.

(b) *Vitamin addition (optional).* (1) If added, vitamin A shall be present in such quantity that each 946 milliliters (quart) of the food contains not less than 2,000 International Units thereof, within limits of good manufacturing practice.

(2) If added, vitamin D shall be present in such quantity that each 946 milliliters (quart) of the food contains 400 International Units thereof, within limits of good manufacturing practice.

(c) *Optional dairy ingredients.* Cream, milk, partially skimmed milk, or skim milk, used alone or in combination.

(d) *Other optional ingredients.* (1) Concentrated skim milk, nonfat dry milk, buttermilk, whey, lactose, lactalbumins, lactoglobulins, or whey modified by partial or complete removal of lactose and/or minerals, to increase the nonfat solids content of the food:

Provided, That the ratio of protein to total nonfat solids of the food, and the protein efficiency ratio of all protein present shall not be decreased as a result of adding such ingredients.

(2) Nutritive carbohydrate sweeteners. Sugar (sucrose), beet or cane; invert sugar (in paste or sirup form); brown sugar; refiner's sirup; molasses (other than blackstrap); high fructose corn sirup; fructose; fructose sirup; maltose; maltose sirup, dried maltose sirup; malt extract, dried malt extract; malt sirup, dried malt sirup; honey; maple sugar; or any of the sweeteners listed in Part 168 of this chapter, except table sirup.

(3) Flavoring ingredients.

(4) Color additives that do not impart a color simulating that of milkfat or butterfat.

(5) Stabilizers.

(6) Butterfat or milkfat, in the form of flakes or granules.

(7) Aroma- and flavor-producing microbial culture.

(8) Salt.

(9) Citric acid, in a maximum amount of 0.15 percent by weight of the milk used, or an equivalent amount of sodium citrate, as a flavor precursor.

(e) *Methods of analysis.* The following referenced methods of analysis are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th ed., 1980,[1] which is incorporated by reference.

(1) Milkfat content—As determined by the method prescribed in section 16.059, "Roese-Gottlieb Method (Reference Method) (11)—Official Final Action," under the heading "Fat."

(2) Milk solids not fat content—Calculated by subtracting the milkfat content from the total solids content as determined by the method prescribed in section 16.032, "Method I—Official Final Action," under the heading "Total Solids."

(3) Titratable acidity—As determined by the method prescribed in section 16.023, "Acidity (2)—Official Final Action," or by an equivalent potentiometric method.

(f) *Nomenclature.* The name of the food is "cultured skim milk" or alternatively, "cultured nonfat milk". The full name of the food shall appear on the principal display panel of the label in type of uniform size, style and color. The name of the food shall be accompanied by a declaration indicating the presence of any characterizing flavoring as specified in § 101.22 of this chapter, and may be accompanied by a declaration such as a traditional name of the food or the generic name of the organisms used, thereby indicating the presence of the characterizing microbial organisms or ingredients, e.g., "kefir cultured nonfat milk", "acidophilus cultured nonfat milk", or when characterizing ingredients such as those in paragraph (d) (6), (7), (8), and (9) of this section, and lactic acid-producing organisms are used the food may be named "cultured skim milk buttermilk" or alternatively "cultured nonfat buttermilk".

(1) The following terms shall accompany the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half of the height of the letters used in such name.

(i) The phrase "vitamin A" or "vitamin A added" or "vitamin D" or "vitamin D added", or "vitamins A and D added", as appropriate. The word "vitamin" may be abbreviated "vit.".

(ii) The word "sweetened" if nutritive carbohydrate sweetener is added without the addition of characterizing flavoring.

(2) The term "homogenized" may appear on the label if the dairy ingredients used are homogenized.

(g) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

§ 131.170 Eggnog.

(a) *Description.* Eggnog is the food containing one or more of the optional dairy ingredients specified in paragraph (b), one or more of the optional egg yolk-containing ingredients specified in paragraph (c) of this section, and one or more of the optional nutritive carbohydrate sweeteners specified in paragraph (d) of this section. One or more of the optional ingredients specified in paragraph (e) of this section may also be added. All ingredients used are safe and suitable. Eggnog contains not less than 6 percent milkfat and not less than 8.25 percent milk solids not fat. The egg yolk solids content is not less than 1 percent by weight of the finished food. The food shall be pasteurized or ultra-pasteurized and may be homogenized.

(b) *Optional dairy ingredients.* Cream, milk, partially skimmed milk, or skim milk, used alone or in combination.

(c) *Egg yolk-containing ingredients.* Liquid egg yolk, frozen egg yolk, dried egg yolk, liquid whole eggs, frozen whole eggs, dried whole eggs, or any one or more of the foregoing ingredients with liquid egg white or frozen egg white.

(d) *Nutritive carbohydrate sweeteners.* Sugar (sucrose), beet or cane; invert sugar (in paste or sirup form); brown sugar; refiner's sirup; molasses (other than blackstrap); high fructose corn sirup; fructose; fructose sirup; maltose; maltose sirup, dried maltose sirup; malt extract, dried malt extract; malt sirup, dried malt sirup; honey; maple sugar; or any of the sweeteners listed in Part 168 of this chapter, except table sirup.

(e) *Other optional ingredients.* (1) Concentrated skim milk, nonfat dry milk, buttermilk, whey, lactose, lactalbumins, lactoglobulins, or whey modified by partial or complete removal of lactose and/or minerals, to increase the nonfat solids content of the food: *Provided,* That the ratio of protein to total nonfat solids of the food, and the protein efficiency ratio of all protein present shall not be decreased as a result of adding such ingredients.

(2) Salt.

(3) Flavoring ingredients.

(4) Color additives that do not impart a color simulating that of egg yolk, milkfat, or butterfat.

(5) Stabilizers.

(f) *Methods of analysis.* The following referenced methods of analysis are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th ed., 1980,[1] which is incorporated by reference.

(1) Milkfat content—As determined by the method prescribed in section 16.059, "Roese-Gottlieb Method (Reference Method) (11)—Official Final Action," under the heading "Fat."

(2) Milk solids not fat content—Calculated by subtracting the milkfat content from the total solids content as determined by the method prescribed in section 16.032, "Method I—Official Final Action," under the heading "Total Solids."

(g) *Nomenclature.* The name of the food is "eggnog". The name of the food shall be accompanied by a declaration indicating the presence of any characterizing flavoring as specified in § 101.22 of this chapter. If the food is ultra-pasteurized, the phrase "ultra-pasteurized" shall accompany the name of the food wherever it appears on the label in letters not less than one-half of the height of the letters used in the name. The following terms may accompany the name of the food on the label:

(1) The word "pasteurized" if the food has been pasteurized.

(2) The word "homogenized" if the food has been homogenized.

(h) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

§ 131.200 Yogurt.

(a) *Description.* Yogurt is the food produced by culturing one or more of the optional dairy ingredients specified in paragraph (b) of this section with a characterizing bacterial culture that contains the lactic acid-producing bacteria, *Lactobacillus bulgaricus* and *Streptococcus thermophilus.* One or more of the other optional ingredients specified in paragraph (c) of this section may also be added. When one or more of the ingredients specified in paragraph (c)(1) of this section are used, they shall be included in the culturing process. All ingredients used are safe and suitable. Yogurt, before the addition of bulky flavors, contains not less than 3.25 percent milkfat and not less than 8.25 percent milk solids not fat, and has a titratable acidity of not less than 0.9 percent, expressed as lactic acid. The food may be homogenized and shall be pasteurized or ultra-pasteurized prior to the addition of the bacterial culture and bulky flavoring material. To extend the shelf life of the food, yogurt may be heat treated after culturing is completed, to destroy viable microorganisms.

(b) *Optional dairy ingredients.* Cream, milk, partially skimmed milk, or skim milk, used alone or in combination.

(c) *Other optional ingredients.* (1) Concentrated skim milk, nonfat dry milk, buttermilk, whey, lactose, lactalbumins, lactoglobulins, or whey modified by partial or complete removal of lactose and/or minerals, to increase the nonfat solids content of the food: *Provided,* That the ratio of protein to total nonfat solids of the food, and the protein efficiency ratio of all protein present shall not be decreased as a result of adding such ingredients.

(2) Nutritive carbohydrate sweeteners. Sugar (sucrose), beet or cane; invert sugar (in paste or sirup form); brown sugar; refiner's sirup; molasses (other than blackstrap); high fructose corn sirup; fructose; fructose sirup; maltose; maltose sirup, dried maltose sirup; malt extract, dried malt extract; malt sirup, dried malt sirup; honey; maple sugar; or any of the sweeteners listed in Part 168 of this chapter, except table sirup.

(3) Flavoring ingredients.

(4) Color additives.

(5) Stabilizers.

(d) *Methods of analysis.* The following referenced methods of analysis are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th ed., 1980,[1] which is incorporated by reference.

(1) Milkfat content—As determined by the method prescribed in section 16.059 "Roese-Gottlieb Method (Reference Method) (11)—Official Final Action," under the heading "Fat."

(2) Milk solids not fat content—Calculated by subtracting the milkfat content from the total solids content as determined by the method prescribed in section 16.032, "Method I—Official Final Action," under the heading "Total Solids."

(3) Titratable acidity—As determined by the method prescribed in section 16.023, "Acidity (2)—Official Final Action," or by an equivalent potentiometric method.

(e) *Nomenclature.* The name of the food is "yogurt". The name of the food shall be accompanied by a declaration indicating the presence of any characterizing flavoring as specified in § 101.22 of this chapter.

(1) The following terms shall accompany the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half of the height of the letters used in such name:

(i) The word "sweetened" if nutritive carbohydrate sweetener is added without the addition of characterizing flavor.

(ii) The parenthetical phrase "(heat-treated after culturing)" shall follow the name of the food if the dairy ingredients have been heat-treated after culturing.

(2) The term "homogenized" may appear on the label if the dairy ingredients used are homogenized.

(f) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

§ 131.203 Lowfat yogurt.

(a) *Description.* Lowfat yogurt is the food produced by culturing one or more of the optional dairy ingredients specified in paragraph (b) of this section with a characterizing bacterial culture that contains the lactic acid-producing bacteria, *Lactobacillus bulgaricus* and *Streptococcus thermophilus.* One or more of the other optional ingredients specified in paragraph (c) of this section may also be added. When one or more of the ingredients specified in paragraph (c)(1) of this section are used, they shall be included in the culturing process. All ingredients used are safe and suitable. Lowfat yogurt, before the addition of bulky flavors, contains not less than 0.5 percent nor more then 2 percent milkfat and lot less than 8.25 percent milk solids not fat, and has a titratable acidity of not less than 0.9 percent, expressed as lactic acid. The food may be homogenized and shall be pasteurized or ultra-pasteurized prior to the addition of the bacterial culture and bulky flavoring material. To extend the shelf life of the food, lowfat yogurt may be heat-treated after culturing is completed, to destroy viable microorganisms.

(b) *Optional dairy ingredients.* Cream, milk, partially skimmed milk, or skim milk, used alone or in combination.

(c) *Other optional ingredients.* (1) Concentrated skim milk, nonfat dry milk, buttermilk, whey, lactose, lactalbumins, lactoglobulins, or whey modified by partial or complete removal of lactose and/or minerals, to increase the nonfat solids content of the food: *Provided,* That the ratio of protein to total nonfat solids of the food, and the protein efficiency ratio of all protein present shall not be decreased as a result of adding such ingredients.

(2) Nutritive carbohydrate sweeteners. Sugar (sucrose), beet or cane; invert sugar (in paste or sirup form); brown sugar; refiner's sirup; molasses (other than blackstrap); high fructose corn sirup; fructose; fructose sirup; maltose, maltose sirup, dried maltose sirup; malt extract, dried malt extract; malt sirup, dried malt sirup; honey; maple sugar; or any of the sweeteners listed in Part 168 of this chapter, except table sirup.

(3) Flavoring ingredients.

(4) Color additives.

(5) Stabilizers.

(d) *Methods of analysis.* The following referenced methods of analysis are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th ed., 1980,[1] which is incorporated by reference.

(1) Milkfat content—As determined by the method prescribed in section 16.059 "Roese-Gottlieb Method (Reference Method) (11)—Official Final Action," under the heading "Fat."

(2) Milk solids not fat content—Calculated by subtracting the milkfat content from the total solids content as determined by the method prescribed in section 16.032, "Method I—Official Final Action," under the heading "Total Solids."

(3) Titratable acidity—As determined by the method prescribed in section 16.023, "Acidity (2)—Official Final Action," or by an equivalent potentiometric method.

(e) *Nomenclature.* The name of the food is "lowfat yogurt". The full name of the food shall appear on the principal display panel of the label in type of uniform size, style, and color. The name of the food shall be accompanied by a declaration indicating the presence of any characterizing flavoring as specified in § 101.22 of this chapter.

(1) The following terms shall accompany the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half of the height of the letters used in such name.

(i) The phrase "— percent milkfat", the blank to be filled in with the fraction ½ or multiple thereof closest to the actual fat content of the food.

(ii) The word "sweetened" if nutritive carbohydrate sweetener is added without the addition of characterizing flavoring.

(iii) The parenthetical phrase "(heat-treated after culturing)" shall follow the name of the food if the dairy ingredients have been heat-treated after culturing.

(2) The term "homogenized" may appear on the label if the dairy ingredients used are homogenized.

(f) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

§ 131.206 Nonfat yogurt.

(a) *Description.* Nonfat yogurt is the food produced by culturing one or more of the optional dairy ingredients specified in paragraph (b) of this section with a characterizing bacterial culture that contains the lactic acid-producing bacteria, *Lactobacillus bulgaricus* and *Streptococcus thermophilus*. One or more of the other optional ingredients specified in paragraph (c) of this section may also be added. When one or more of the ingredients specified in paragraph (c)(1) of this section are used, they shall be included in the culturing process. All ingredients used are safe and suitable. Nonfat yogurt, before the addition of bulky flavors, contains less than 0.5 percent milkfat and not less than 8.25 percent milk solids not fat, and has a titratable acidity of not less than 0.9 percent, expressed as lactic acid. The food may be homogenized and shall be pasteurized or ultra-pasteurized prior to the addition of the bacterial culture and bulky flavoring material. To extend the shelf life of the food, nonfat yogurt may be heat-treated after culturing is completed, to destroy viable microorganisms.

(b) *Optional dairy ingredients.* Cream, milk, partially skimmed milk, or skim milk, used alone or in combination.

(c) *Other optional ingredients.* (1) Concentrated skim milk, nonfat dry milk, buttermilk, whey, lactose, lactalbumins, lactoglobulins, or whey modified by partial or complete removal of lactose and/or minerals, to increase the nonfat solids content of the food: *Provided*, That the ratio of protein to total nonfat solids of the food, and the protein efficiency ratio of all protein present shall not be decreased as a result of adding such ingredients.

(2) Nutritive carbohydrate sweeteners. Sugar (sucrose), beet or cane; invert sugar (in paste or sirup form); brown sugar; refiner's sirup; molasses (other than blackstrap); high fructose corn sirup; fructose; fructose sirup; maltose; maltose sirup, dried maltose sirup; malt extract, dired malt extract; malt sirup, dried malt sirup; honey; maple sugar; or any of the sweeteners listed in Part 168 of this chapter, except table sirup.

(3) Flavoring ingredients.

(4) Color additives.

(5) Stabilizers.

(d) *Methods of analysis.* The following referenced methods of analysis are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th ed., 1980,[1] which is incorporated by reference.

(1) Milkfat content—As determined by the method prescribed in section 16.059, "Roese-Gottlieb Method (Reference Method) (11)—Official Final Action," under the heading "Fat."

(2) Milk solids not fat content—Calculated by subtracting the milkfat content from the total solids content as determined by the method prescribed in section 16.032, "Method I—Official Final Action," under the heading "Total Solids."

(3) Titratable acidity—As determined by the method prescribed in section 16.023, "Acidity (2)—Official Final Action," or by an equivalent potentiometric method.

(e) *Nomenclature.* The name of the food is "nonfat yogurt". The full name of the food shall appear on the principal display panel of the label in type of uniform size, style, and color. The name of the food shall be accompanied by a declaration indicating the presence of any characterizing flavoring as specified in § 101.22 of this chapter.

(1) The following terms shall accompany the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half of the height of the letters used in such name:

(i) The word "sweetened" if nutritive carbohydrate sweetener is added without the addition of characterizing flavoring.

(ii) The parenthetical phrase "(heat-treated after culturing)" shall follow the name of the food if the dairy ingredients have been heat-treated after culturing.

(2) The term "homogenized" may appear on the label if the dairy ingredients used are homogenized.

(f) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

Any person who will be adversely affected by the foregoing regulation may at any time on or before March 2, 1981, submit to the Dockets Management Branch (formerly the Hearing Clerk's office) (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, written objections thereto and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection is made. Each numbered objection on which a hearing is requested shall specifically so state; failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held; failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Four copies of all documents shall be submitted and shall be identified with the Dockets Management Branch docket number found in brackets in the heading of this regulation. Received objections may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Effective date. Except as to any provisions that may be stayed by the filing of proper objections, compliance with this final regulation, including any required labeling changes, may begin March 31, 1981, and all affected products initially introduced or initially delivered for introduction into interstate commerce on or after July 1, 1983, shall fully comply. Notice of the filing of objections or lack thereof will be published in the Federal Register.

(Secs. 401, 701(e), 52 Stat. 1046 as amended, 70 Stat. 919 as amended (21 U.S.C. 341, 371(e)))

Dated: January 19, 1981.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

Note.—Incorporation by reference provisions approved by the Director of the Office of the Federal Register on September 19, 1980, and is on file at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 20408.

[FR Doc. 81-3129 Filed 1-28-81; 8:45 am]

BILLING CODE 4110-03-M